

# EXHIBIT 6

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR  
SYSTEM PRODUCTS LIABILITY  
LITIGATION

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MDL NO. 2327

THIS DOCUMENT RELATES TO:  
Mullins, et al.

2:12-cv-02952

*And all actions consolidated therewith*

**RULE 26 SUPPLEMENTAL EXPERT REPORT OF BRUCE ROSENZWEIG, M.D.**

**I. QUALIFICATIONS.**

I am currently an Assistant Professor of Obstetrics and Gynecology at Rush University Medical Center in Chicago, Illinois. I received my MD degree in 1984 from the University of Michigan in Ann Arbor, Michigan. Following graduation from medical school, I completed an Obstetrics and Gynecology Residency at Michael Reese Hospital in Chicago. In 1988, I attended a one year pelvic surgery fellowship at State University of New York in Syracuse, New York. Following that fellowship, I attended a two year Urogynecology and Urodynamics fellowship at UCLA Harbor General Hospital in Torrance, California. After graduating from the Urogynecology fellowship, I became a faculty member at the University of Illinois in Chicago. I started a Urogynecology program at the University of Illinois and also was the residency program director. In 1998, I went into private practice, and subsequently established a private practice at Rush University Medical Center. I have also worked at John H. Stroger Hospital here in Chicago from May 2003 until November 2010 and Weiss Memorial Hospital as Associate Chair of Gynecology from February 2011 until July 2012. I have published numerous articles and given numerous lectures on the topics of pelvic organ prolapse, urinary

incontinence and repair of pelvic organ prolapse.

Throughout my career, I have performed over a thousand pelvic floor surgical procedures, including abdominal sacrocolpopexy, uterosacral suspensions, sacrospinous ligament fixations, native tissue repairs, biological graft repairs and synthetic mesh repairs. I have also used numerous synthetic pelvic mesh products, including Ethicon's TVT, TVTbturator, and Prolift. In addition, I have performed over 300 surgeries dealing with complications related to synthetic mesh, including the removal of numerous TVT devices. I have also treated approximately 800 additional patients with mesh non-surgically. I was invited by Ethicon and attended both its Gynecare Prolift Training Seminar and TVT Obturator Seminar in Belgium. In addition, I was invited and attended a Bard Avaulta training seminar in the past.

A copy of my CV and Fee Schedule is attached as Exhibit "A" and a copy of my testimony for the last four years is attached as Exhibit "B". The documents I relied on for this report are contained in Exhibit "C" as well as those documents cited throughout this Report.

## **II. SUMMARY OF OPINIONS.**

In formulating my opinions and preparing this report, I reviewed scientific literature, corporate documents from Ethicon, sample products and depositions of Ethicon employees and witnesses. The corporate documents, sample products and depositions were supplied to me by counsel. A list of Ethicon corporate documents and depositions reviewed for this report is attached hereto as Exhibit "C"; other materials reviewed are listed at the end of this report. All opinions I have are to a reasonable degree of medical and scientific certainty. I understand discovery is still ongoing in this case, and I reserve my right to amend my opinions if further information is provided in any form including, but not

limited to corporate documents, depositions and the expert reports of both Plaintiff and Defense experts. My opinions in this Report relate only to the Ethicon Design Consolidation case pending in West Virginia.

In general, my expert opinions can be summarized as follows<sup>1</sup>:

- A. Ethicon's old construction mesh (Prolene), used in the TVT, is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence because the pores are too small, it is heavy weight mesh, it degrades over time, causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, biofilm formation and infections, has sharp edges, ropes, curls and deforms, and the pores collapse with tension;
- B. Ethicon knew that the old construction mechanically cut mesh (Prolene) was not appropriate for use in its TVT device but has failed to modify/change the mechanically cut mesh to a larger pore, lighter weight mesh that would not deform, fray, lose particles, rope, curl, degrade, cause excessive foreign body reactions, and cause excessive shrinkage/contraction. According to Ethicon's internal documents, Ethicon was unwilling to change the mesh because of its economic interest in maintaining its competitive advantage in the MUS market and, therefore, Ethicon put profits before patient safety;
- C. Ethicon's TVT's design is flawed because it cannot adequately describe, inform or explain to physicians how to properly "tension" the TVT and the mesh shrinks, contracts, ropes and curls making it difficult or impossible to tension in a safe manner for patients;
- D. Ethicon's Prolene mesh in the TVT is not suitable for permanent implant because the Material Safety Data Sheets ("MSDS") for polypropylene resin used to manufacture polypropylene states that polypropylene is incompatible with strong oxidizers such as peroxides which are readily found in the vagina;
- E. Ethicon's Prolene mesh is also not suitable for permanent implant because the toxicity testing of the polypropylene mesh revealed that it was cytotoxic which can cause cell death and complications;
- F. Ethicon's warnings and disclosures of adverse events in its TVT Instructions for Use ("IFU") have been inadequate based on the adverse reactions and risks associated with the TVT that have been known to Ethicon from the time the TVT was first sold and marketed, and Ethicon did not disclose information to physicians in its IFUs regarding characteristics of the old construction mesh

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<sup>1</sup> This is not intended to be an exhaustive recitation of my opinions in this case. The full scope of my opinions are described in further detail in this report.

(Prolene) that makes it unsuitable for its intended application as a permanent prosthetic implant for stress urinary incontinence, including that it is small pore, heavy weight mesh, it degrades over time, causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, roping and curling of the mesh, that it deforms and the pores collapse with tension, that it is difficult or impossible to tension; that it tested positive for cytotoxicity and that the MSDS states that it is incompatible with strong oxidizers such as peroxides.

- G. The design of the TVT device is flawed because it is not designed for special patient populations nor does the IFU or marketing documents inform physicians that certain patients will have poorer outcomes and higher risks.
- H. Ethicon failed to reveal material facts about complication and conflict of interests regarding key studies and in key marketing documents.
- I. The benefits of the TVT are outweighed by the severe, debilitating and life changing complications associated with the TVT and there were safer alternative options available.
- J. It has been known since the launch of the TVT that the mesh can be difficult to remove, is susceptible to degradation, can rope, curl, deform, fray, and lose particles, and is a heavy weight mesh. However, Ethicon did not account for this facts in its dFMEA at the time of launch, and has failed to complete a proper risk analysis of these hazards

### **III. BACKGROUND AND TREATMENT OPTIONS FOR STRESS URINARY INCONTINENCE.**

#### **A. Stress Urinary Incontinence (“SUI”)**

Approximately one of three women over the age of 45 years old has some form of urinary incontinence. The majority of those women do not seek medical advice or treatment for a variety of reasons.

In a continent individual, increased abdominal pressure is evenly distributed over the bladder, bladder neck, and urethra. The urethral sphincter is thus able to withstand this pressure and maintain continence. In a person with pure stress urinary incontinence (SUI), either the urethra is hypermobile or the sphincter is intrinsically deficient. In urethral hypermobility, the urethrovesical junction (UVJ) is displaced extra-abdominally, and the

increased intra-abdominal pressure is unevenly distributed such that the sphincter can no longer withstand the pressure and urine leaks. With intrinsic sphincter deficiency (ISD), the UVJ is not hypermobile; however, the maximal urethral closing pressure, the Valsalva leak-point pressure, or both are too low to withstand the increase in intra-abdominal pressure and, thus, urine leaks past the sphincter.

SUI is the involuntary leakage of urine during moments of physical activity that increases abdominal pressure, such as coughing, sneezing, laughing, or exercise, in the absence of a bladder contraction. It has been estimated that 14% of women have SUI. SUI is a common type of urinary incontinence in women. Urodynamic proven SUI is found in approximately 50% of women presenting for evaluation of urinary incontinence. Symptomatic women with SUI have social or hygienic consequence from their urine loss. SUI can happen when pelvic tissues and muscles, which support the bladder and urethra, become weak and allow the bladder “neck” (where the bladder and urethra intersect) to descend during bursts of physical activity (urethral hypermobility). This descent can prevent the urethra from working properly to control the flow of urine. SUI can also occur when the sphincter muscle that controls the urethra weakens (intrinsic sphincter deficiency). The weakened sphincter muscle is not able to stop the flow of urine under normal circumstances, and when there is an increase in abdominal pressure. Weakness may occur from pregnancy, childbirth, aging, or prior pelvic surgery. It has been estimated that a majority of incontinent women have a combination of urethral hypermobility and ISD. Other risk factors for SUI include chronic coughing or straining, constipation, obesity and smoking. Finally occult or latent SUI is defined as a positive stress test, loss of urine with increased intra-abdominal pressure and between 350-450cc volume in the bladder, after the repositioning of pelvic organ prolapse (usually

accomplished with a ring pessary carefully positioned as to avoid compression of the urethra) in an otherwise clinically continent patient.

**B. Nonsurgical Treatment of SUI.**

There are numerous non-surgical treatments available to woman with SUI. First, Pelvic Floor Exercises: A type of exercise to strengthen the pelvic floor by contracting and relaxing the levator muscles that surround the opening of the urethra, vagina, and rectum. These exercises, commonly referred to as Kegel exercises, improve the pelvic floor muscles' strength and function. Kegel exercises can improve over-active bladders by increasing urethral resistance which can trigger the bladder to relax.

Second, Pessary: A removable device that is inserted into the vagina against the vaginal wall and urethra to support the bladder neck. This helps reposition the urethra to reduce SUI. These can be made of rubber, latex or silicon. Inserted into the vagina, a pessary rests against the back of the pubic bone and supports the bladder. Pessaries are available in various forms, including donut and cube shapes, and must be fitted by a healthcare provider. Some women who have stress incontinence use a pessary just during activities that are likely to cause urine leakage, such as jogging. Special incontinence pessaries have a 'knob', which fits under the urethra to elevate the midurethral to prevent urine loss.

Third, Transurethral Bulking Agents: Bulking agent injections are applied around the urethra that makes the space around the urethra thicker, thus helping to control urine leakage. The effects are usually not permanent.

Fourth, Behavioral Modification: This includes avoiding activities that trigger episodes of leaking. Lifestyle modification can improve stress incontinence symptoms and include quitting smoking, weight loss, and allergy treatment during seasonal allergies.

Fifth, Urinary seals: These are adhesive foam pads, which women place over the urethral opening. The pad creates a seal and prevents the leakage of urine, providing incontinence treatment. The pad is removed before urination and replaced with a new one afterward. The pad can be worn during exercise or physical activity, but not during sexual intercourse.

Sixth, Urethral insert: A thin, flexible tube that is solid rather than hollow (like a catheter) is placed into the urethra to block the leakage of urine. These small plugs are inserted into the urethra by women to prevent leakage, and are removed prior to urination. These inserts can be uncomfortable and may increase the risk of urinary tract infection.

Seventh, Bladder neck support device: This device is a flexible ring with two ridges. Once inserted into the vagina, the ridges press against the vaginal walls and support the urethra. By lifting the bladder neck, it provides better bladder control in women suffering from stress incontinence. The device needs to be sized to fit, and must be removed and cleaned after urination. Bladder neck support devices can be uncomfortable and may cause urinary tract infections.

### **C. Surgical Treatment of SUI.**

#### **1. The Burch Colposuspension.**

Retropubic approaches for the treatment of stress urinary incontinence include the Burch retropubic urethropexy (both open and laparoscopic) and the Marshall-Marchetti-Krantz (MMK) procedure. The goal of both of these procedures is to suspend and stabilize the urethra so that the urethrovesical junction (UVJ) and proximal urethra are replaced intra-abdominally and to recreate a firm backstop for intra-abdominal pressure. This anatomic placement allows normal pressure transmission during periods of increased intra-abdominal pressure restoring continence in a previously incontinent, hypermobile UVJ.

The Burch procedure was described in 1961. Initially, Burch described attaching the paravaginal fascia to the arcus tendineus. However, this was later changed to Cooper's ligaments because these were felt to provide more secure fixation points, and less chance of infection as seen with the prior MMK procedure.

Patients with type III stress urinary incontinence (a fixed, nonfunctioning proximal urethra) are not ideal candidates for a Burch procedure as no hypermobility exists to correct. For the Burch procedure, a low Pfannestiel incision is made above the pubic bone in order to enter the space of Retzius (the anatomical space between the pubic bone and the bladder above the peritoneum in order to suspend the bladder and/or to perform a paravaginal repair. The procedure involves placing permanent stitches adjacent to the neck of the bladder and either proximal or distal to the bladder neck stitches on each side and suturing them Cooper's ligament which is attached to the pubic bone. The paravaginal repair is very similar except that the stitches are attached to the arcus tendentious linea pelvis. The likelihood of success of the Burch and the paravaginal repair procedures is reported to be 80-90% in most cases. Success means total elimination of the incontinence and patient satisfaction score greater than 90%. Improved means significant reduction of urine loss and greater than 70% improvement of patient satisfaction scores. Additionally, these retropubic procedures can be accomplished by the laparoscopic route. With respect to the selection of synthetic absorbable suture versus non-absorbable suture, and braided versus monofilament, no prospective randomized blinded data exist to suggest superiority of one suture material over another. However, recognized risks are associated with bone anchors. Modifications in the technique can be used if co-existent central defect cystocele is present and obliteration of the cul-de-sac can be performed to prevent enterocele or posterior vaginal wall prolapse after Burch colposuspension.

Although the Burch procedure may take longer and require a very small hospitalization, it is a much safer procedure than synthetic slings because life-altering long-term complications do not occur with Burch like they do with synthetic slings, including chronic debilitating pain, chronic sexual dysfunction and dyspareunia, erosions, multiple surgeries to remove mesh, emotional issues related to sexual dysfunction and many others as discussed throughout this report. Furthermore, if complications do occur following a Burch procedure, they are very rarely long-term and much easier to treat.

## **2. Pubovaginal sling procedures.**

Pubovaginal slings have excelled overall success and durable cure. The procedure involves placing a band of autologous, allograft, xenograft or synthetic material directly under the bladder neck (ie, proximal urethra) or mid-urethra, which acts as a physical support to prevent bladder neck and urethral descent during physical activity. This is brought up through the rectus fascia. The sling also may augment the resting urethral closure pressure with increases in intra-abdominal pressure.

Historically, surgeons have used the fascia lata sling for recurrent SUI after a failed anti- incontinence operation. Furthermore, this operation is used extensively for the treatment of primary ISD. If the abdominal tissues are weak and attenuated or if the vaginal tissues are atrophied or in short supply, constructing a pubovaginal sling from the leg fascia lata can be performed. This procedure is more involved than the creation of the rectus fascial sling as it requires a second incision to harvest the fascia lata and healing in an area remote for the index procedure.

An alternative to a long rectus sling is construction of a short sling from a much smaller piece of abdominal fascia (rectus fascia suburethral sling). The surgical procedure is similar to

that used for the rectus fascia pubovaginal sling, except that the harvested fascial tissue is much smaller and the operation time shorter. The advantage of this procedure is its simplicity. No extensive dissection in the suprapubic area is necessary, and the postoperative result is similar to that of the full-length fascial strip sling.

An alternative to a long fascia lata sling is the use of a postage stamp–sized patch of fascia lata from the outer thigh (fascia lata suburethral sling). The surgical procedure is similar to that for the fascia lata pubovaginal sling, except the harvested fascia is much smaller. This operation does not require extensive dissection in the thigh area, and the postoperative result is similar to that of the full-length fascia lata strip sling. Postoperative convalescence is shorter than that of the fascia lata pubovaginal sling procedure.

The vaginal wall suburethral sling helps restore urethral resistance by increasing urethral compression and improving mucosal coaptation of the bladder neck. This operation is attractive because it is simple and easy to perform. Postoperative complications are minimal, and the recuperative period is short. Vaginal sling surgery is relatively contraindicated in elderly women with atrophic vaginitis. If recognized before surgery, the atrophied vaginal wall may be revitalized with the administration of vaginal estrogen cream or tablets for 3-6 months.

A clear contraindication to pubovaginal sling surgery is pure urge incontinence or mixed urinary incontinence (MUI) in which urge is the predominant component. An inherent risk of any sling procedure is de novo or worsening urge symptoms; thus, surgeons must identify and treat the presence of an urge component before surgery.

Conversely, poor detrusor function is a relative contraindication to pubovaginal sling surgery because the potential for urinary retention is increased. Women with absent or poor detrusor function in the presence of SUI are at a higher risk of experiencing prolonged

postoperative urinary retention.

### **3. Midurethral Synthetic Slings.**

Based on the “Integral theory of female incontinence,” Prof. Ulmsten developed a midurethral procedure to treat stress urinary incontinence. The first reports of this procedure appeared in 1996 as an intravaginal slingoplasty. The “tape” was placed through a small vaginal incision at the midurethra, brought through the urogenital diaphragm through the retropubic space and exited through small suprapubic incisions. The operation was theorized to correct incontinence by recreating the midurethral support of the pubourethral ligament and also by creating a midurethral hammock for support of the urethra during stress events. The procedure was described to have a success rate of 85-90% with an additional 5-10% significantly improved. The Gynecare TVT system was introduced in the US in November of 1998. Early studies showed that the risk of bladder perforation during the procedure occurred 5-10% of cases and vascular injury with or without hematoma formation occurred in 2-5% of patients.

In an attempt to decrease the risk of bladder perforation and vascular injury, a “top-down” approach to trocar placement was promoted as the SPARC procedure, introduced in the US in 2001 by American Medical Systems (AMS). The next modification of the midurethral sling came in 2001 when Delorme described his results for the use of the obturator membrane and inner thigh for passage of the sling material. The proposed advantage was avoidance of the retropubic space, thus avoiding bladder perforation and retropubic vascular injury. The trocars were passed from the inner thigh through the obturator membrane from an “outside – in direction”.

The next modification came from de Leval in 2003, with the “inside-out” trocar placement for the transobturator sling. This device is the focus of this report. The final

modification came around 2006 with the release of the mini-slings, or single incision slings, which use support devices at the ends of shorter mesh lengths to accomplish fixation without the need for a secondary cutaneous exit point. The mini-slings could be placed in a retropubic or “U” fashion or a hammock or “H” fashion.

The FDA concluded in 2011 that there was higher peri-operative blood loss, higher mesh exposure and greater need for surgical re-intervention in the TVT-Secur (mini-sling) patients.

#### IV. EXPERT OPINIONS

- A. Ethicon’s old construction mesh (Prolene), used in the TVT, is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence because the pores are too small, it is heavy weight mesh, it degrades over time, causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, biofilm formation and infections, sharp edges, roping and curling of the mesh, it deforms, and the pores collapse with tension.**

Polypropylene mesh (Prolene), like that contained in the TVT, has many well-known characteristics that make it unsuitable for use as a product intended for permanent implantation in the human vaginal floor. These characteristics include the following: (1) degradation of the mesh; (2) chronic foreign body reaction; (3) infections and bio-films; (4) fraying, roping, curling and deformation of the mesh; (5) loss of pore size with tension; (6) fibrotic bridging leading to scar plate formation and mesh encapsulation; and (7) shrinkage/contraction of the encapsulated mesh.

As a result of these and other inadequacies with the mesh, and for the reasons set forth below, it is my opinion to a reasonable degree of medical certainty that the Prolene polypropylene mesh in the TVT causes a multitude of injuries, including the possibility of multiple erosions that can occur throughout one’s lifetime, chronic and debilitating pelvic pain,

recurrence, worsening incontinence, chronic dyspareunia, nerve injury of the pelvic nerves, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, Ethicon's TVT mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

### **1. The Prolene Mesh in TVT Degrades Over Time**

As noted below, the mesh used in the TVT was originally designed in 1974 for use in the abdomen for treatment of hernias and it has not changed since then.<sup>2</sup> Ethicon describes this mesh as the "old, old" mesh: "The first generation (old, old) mesh is utilized currently in the TVT product...."<sup>3</sup> The current Material Specifications for TVT Mesh list it as: "Old Construction PROLENE\* Mesh."<sup>4</sup> Dan Smith testified that even when the original hernia mesh was updated for use in the abdomen, Ethicon continued to use the "old, old" mesh for TVT and does to this day, as follows:

Q: So TVT kept the old when hernia changed to the new.  
 A: Also known as original, yes.  
 Q: The mesh that was used in the TVT-R is called sometimes by Ethicon in documents old construction or original mesh; correct?  
 A: Yes. Yes.<sup>5</sup>

In the late 90's Ethicon determined that, in the hernia applications, it was safer to move to a lighter weight, larger pore mesh. Ethicon made a similar determination for meshes to be used in the pelvic floor.<sup>6</sup> However, Ethicon never updated the "old, old" hernia mesh used in

<sup>2</sup> Smith Dep. (2/3/2014) 723:9-724:6.

<sup>3</sup> Smith Dep. (2/3/2014) 723:9-724:6.

<sup>4</sup> ETH.MESH.10633520 at 3522.

<sup>5</sup> Smith Dep. (2/3/2014) 723:9-724:6.

<sup>6</sup> See, e.g., ETH.MESH.07455220 (discussing mesh shrinkage/contracture and stating: "Since this phenomenon occurs most frequently in small pore, heavy weight mesh, ETHICON has developed large pore, light weight meshes, i.e. GYNECARE GYNEMESH PS Nonabsorbable Prolene Soft Mesh....").

the TVT.<sup>7</sup> Notably, in my opinion this makes science and information regarding hernia meshes and other pelvic meshes of particular relevance when discussing the TVT mesh as Ethicon chose to move to large pore, light weight meshes in these areas, but not for TVT. Moreover, Ethicon relied on science and information regarding hernia meshes to claim the safety and efficacy of their pelvic mesh products to regulatory bodies.

The placement of permanent polypropylene mesh in the human vagina creates problems because of the chemical composition and structure of the mesh and the physiological conditions of the vagina and the surrounding tissues. There have been numerous studies over the last 30 years which have shown polypropylene to be chemically reactive and not inert, with flaking and fissuring demonstrated by scanning electron microscopy, which leads to degradation and release of toxic compounds into pelvic tissues. This process enhances the inflammatory and fibrotic reactions within the tissues in the pelvic floor, causing a multitude of problems.<sup>8</sup> There have been studies suggesting that oxidation of the mesh occurs because of the polypropylene and the conditions in which it is placed.<sup>9</sup> The oxidation causes the mesh to degrade, crack and break apart.<sup>10</sup> In a recent study, 100 pelvic mesh implants were compared and over 20% showed degradation to mesh fibers.<sup>11</sup>

Because of the structural complexities of the vagina and the nature of the chemicals ordinarily found in the vagina and its surrounding tissues, there are several reasons why polypropylene presents unique problems when placed in the vagina. An Engineering

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<sup>7</sup> Smith Dep. (2/3/14) 829:16-829:19.

<sup>8</sup> Coda A., *Hernia* 2003;7:29; Jongebloed, WL, "Degradation of Polypropylene in the Human Eye: A SEM Study," *Doc. Ophthalmol.*, 1986 64(1:143-152); Skrypunch, O.W., "Giant Papillary Conjunctivitis from an Exposed Prolene Suture," *Can. J Ophthalmology*, 198621:(5: 189-192).

<sup>9</sup> Costello C., et al., "Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants from a Single Patient," *Surgical Innovation*, 2007, 143:168- 176).

<sup>10</sup> *Id.*

<sup>11</sup> Clavé A, Yahi H, Hammou JC, Montanari S, Gounon P, Clavé H, "Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants," *J Biomed Mater Res B Appl Biomater*, 2007, Oct

Bulletin from Propex, entitled “*EB-405, The Durability of Polypropylene Geotextiles for Waste Containment Application*,” from 2011, states that, “[P]olypropylene is vulnerable to the following substances: highly oxidized substances such as (peroxide), certain chlorinated hydrocarbons (halogenated hydrocarbons), and certain aromatic hydrocarbons.”<sup>12</sup> It is well known to physicians with expertise in the pelvic floor that vaginal and perivaginal tissues are ready sources for peroxide. The vaginal species lactobacillus produces hydrogen peroxide and lactic acid from collagen that is produced in the squamous cells of the vagina. Estrogen is the catalyst for the production of collagen from the vaginal cells. It is also well known that hydrogen peroxide produced by the lactobacillus species is important in controlling the vaginal micro-flora.

In fact, the vagina is a ready source of hydrogen peroxide production. In a manuscript from M. Strus, “*The In Vitro Effects of Hydrogen Peroxide on Vaginal Microbial Communities*,” the authors show the amount of hydrogen peroxide produced by the lactobacillus species.<sup>13</sup> “Hydrogen Peroxide reached concentrations of from 0.05 to 1.0 mm, which under intensive aeration increases even up to 1.8 mm.”<sup>14</sup> These results confirmed the previous results of M. Strus in the publication, “*Hydrogen Peroxide Produced by Lactobacillus Species as a Regulatory Molecule for Vaginal Micro-flora*,” Med Dosw Mikrobiol, 2004: 56(1:67-77).

It is also known that aromatic hydrocarbons can be found in the human body. In a paper from HB Moon entitled, “*Occurrence and Accumulation Patterns of Polycyclic*

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83(1:44-9).

<sup>12</sup> Citing Schneider H., *Long Term Performance of Polypropylene Geosynthetics, "Durability and Aging of Geosynthetics*, Koerner, RM, Ed., (Elsevier 1989) 95-109.

<sup>13</sup> Strus, M., et al., *The In Vitro Effect of Hydrgen Peroxide in Vaginal Microbial Communities*, FEMS Immunol Med Microbiol, 2006 Oct; 48(1:56-63).

<sup>14</sup> *Id.*

*Aromatic Hydrocarbons and Synthetic Musk Compounds in Adipose Tissues of Korean Females,*” *Chemosphere* 2012 (86:485-490), these aromatic hydrocarbons were noted to be present in, “[t]otal concentrations of PAHs and SMCs in adipose tissues rang[ing] from 15 to 361 (mean:119) ngg(-1) lipid weight and from 38 to 253 (mean:106) nng(-1) lipid weight respectively.... The results of this study provide baseline information on exposure of PAHs and SMCs to the general population in Koreans.”

It has also been determined that halogenated hydrocarbons can be found not only in adipose tissue but also the blood stream. A paper entitled, “*Determination of Volatile Purgeable Halogenated Hydrocarbon in Human Adipose Tissue and Blood Stream,*” from the *Bulletin of Environmental Contamination and Toxicology*, Volume 23, Issue 1, pp 244 – 249 published in 1979, found halogenated hydrocarbons, pesticide by-products, both in human adipose tissues and the blood stream. In a subsequent paper from 1985 in *Environmental Health Perspectives*, Volume 60, pp. 127-131, Henry Anderson, in his paper entitled, “*Utilization of Adipose Tissue Biopsy and Characterizing Human Halogenated Hydrocarbon Exposure,*” also found these pesticide by-products in human adipose tissue. Accordingly, the body location where the polypropylene mesh is being placed can expose it to known chemical degradation agents.

However, chemical degradation is not the only way that polypropylene degrades *in vivo*. In a paper from N Das in the *Journal of Biotechnology Research International*, Volume 2011, Article ID 941810, entitled, “*Review Article: Microbial Degradation of Petroleum Hydrocarbons Contaminant: An Overview,*” found that various bacteria such as *Pseudomonas* species, *Bacillus* species, *Mycobacterium* and *Corynebacterium* species, which are present in a woman’s vagina, can degrade petroleum hydrocarbons. Also fungi such as the *Candida*

species, also present, can degrade petroleum-based hydrocarbons.<sup>15</sup> Microbial agents that can be found inside the normal and abnormal flora of the human vagina such as *Candida* and, with certain pelvic infections such as *Bacillus* and *Pseudomonas*, can be a source of biological degradation of polypropylene products.

A paper entitled, “*Health, Safety and Environment Fact Sheet: Hazardous Substances - Plastics*,” from CAW/TCA ([www.caw.ca](http://www.caw.ca)), August 2011:343, found that polypropylene degradation products and residues can form carbon monoxide, acrolein, aldehydes and acids, qualifying these health hazards as toxic and irritants. In a paper from D Lithner in 2011 at 4, entitled, “*Environmental and Health Hazards of Chemicals in Plastic Polymers and Products*,” University of Gothenburg, it is stated that, “[n]on-biodegradable polymers can be degraded by heat, oxidation, light, ionic radiation, hydrolysis and mechanical shear, and by pollutants such as carbon monoxide, sulphur dioxide, nitrogen oxide and ozone. This causes the polymer to get brittle, to fragment into small pieces and to release degradation products.” (Citations omitted.) Lithner continues, “[o]ther substances (besides monomers) are often needed for polymerization to occur, for instance initiators, catalysts, and, depending on manufacturing process, solvents may also be used. The resulting plastic polymer can be blended with different additives, for instance plasticizers, flame retardants, heat stabilizers, antioxidants, light stabilizers, lubricants, acid scavengers, antimicrobial agents, anti-static agents, pigments, blowing agents and fillers, and is finally processed into a plastic product. There are many different plastic polymers and several thousand different additives, which result in an extremely large variation in chemical composition of plastic products.” *Id.* at 6 (citations omitted). “Since plastic products are composed of many different chemicals, and the main part of these [are] broken down into

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<sup>15</sup> Das, N., et al., *Review Article: Microbial Degradation of Petroleum Hydrocarbon Contaminants: an Overview*, J Biotech Res Intl, 2011, Article ID 941810, 1-13.

something completely different; this complicates the prediction.” *Id.* at 8. “The type and quantity of degradation products formed may also be influenced by degradation mechanisms, presence of polymerization impurities, and surrounding factors, e.g. temperature and oxygen.” *Id.* at 9. “Few studies combining leaching tests with toxicity tests have been performed on plastic products.” *Id.* at 12. The available peer-reviewed literature regarding degradation/oxidation of polypropylene in the human body dates back to the 1960’s and has been reported in numerous such publications.<sup>16</sup>

Two of the more important and salient articles regarding reported degradation in explanted surgical meshes (hernia and pelvic floor) are the Costello and Clave articles. In his paper, “*Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Implants from a Single Patient*,” Prof. C Costello reported that hernia mesh made of polypropylene oxidized and degraded as a result of the metabolites produced by phagocytic cells during the body’s inflammatory reaction to the mesh. High-magnification photographs showed cracking and peeling of the polypropylene fibers. Ethicon referenced this article in internal emails.<sup>17</sup>

Another article by A Clave, “*Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants*,” also displayed high magnification photos of polypropylene fibers from explanted meshes and, in this case, the meshes were explanted from women’s pelvic floor tissue.<sup>18</sup> The heavyweight meshes showed even greater cracking than the lower density meshes, but according to Prof/Dr. Clave, ALL 84 of the polypropylene

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<sup>16</sup> Liebert, T, et al., *Subcutaneous Implants of Polypropylene Filaments*, J Biomed Mater Res. 1976 (10:939-951); Williams, D., *Review of Biodegradation of Surgical Polymers*, J Materials Sci, 1982 (17:1233-1246); Oswald, H.J., et al., *The Deterioration of Polypropylene By Oxidative Degradation*, Polymer Eng Sci, 1965 (5:152-158).

<sup>17</sup> ETH.MESH.005588123.

<sup>18</sup> Clave, A., *Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants*, I Urogynecol J 2010 21:261-270.

explants examined showed degradation. Oxidation of the implanted mesh due to free radical attack through the synthesis of peroxides, superoxides and hypochlorous acid during the chronic inflammatory phase was listed as just one potential cause for the oxidative degradation within the “septic environment” in which the pelvic meshes are placed.

Given the information available to Ethicon in the scientific and medical literature concerning the potential for degradation of polypropylene, it is my opinion to a reasonable degree of medical certainty that Ethicon should have conducted clinically relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene to degrade and if so, what the quantity and quality of the products of degradation would be, whether they would be released into surrounding tissues and/or migrate in the woman’s body, what the clinical implications for the woman would be and whether some women’s bodies would react differently to the mesh and degradative process and its by-products.

Ethicon’s Daniel Burkley, a Principal Scientist at Ethicon, testified that the science supported the conclusion that mesh could shrink, contract and degrade. Specifically, Mr. Burkley agreed that the risk of degradation increases when you have a severe inflammatory response with mesh implanted in a contaminated field.<sup>19</sup> Mr. Burkley also testified that polypropylene mesh in human beings is subject to some slight degree of surface degradation.<sup>20</sup> He agreed that degradation might be better understood if Ethicon studied or tested a product that is permanently implanted in women.<sup>21</sup> In fact, according to Mr. Burkley, Ethicon only conducted one study related to degradation and Prolene material. This study consisted of a Prolene suture implanted into dogs.<sup>22</sup> Mr. Burkley testified that the study and photos from the

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<sup>19</sup> Burkley Dep. (5/22/13) 184:17-24.

<sup>20</sup> Burkley Dep. (5/22/13) 206:2-11

<sup>21</sup> Burkley Dep. (5/22/13) 206:12-25.

<sup>22</sup> ETH.MESH.05453719 (Seven year data for ten year Prolene study: ERF 85-219).

dog actually showed that the Prolene material used in TVT degraded and was still degrading after 7 years.<sup>23</sup>

It is now clear from Ethicon's internal documents that Mr. Burkley was incorrect when he said that Ethicon only performed one study related to degradation of Prolene. Contrary to Mr. Burkley's claim, he and other Ethicon scientists were involved in a Prolene human explant study that was conducted in 1987 which found that Prolene degrades while in the body. According to Ethicon's documents, Ethicon's scientists received 58 Prolene human explants from Professor Robert Guidon<sup>24</sup> which were analyzed by Ethicon's scientists using scanning electron microscopy ("SEM"). The SEM study revealed that 34 of the 58 Prolene explants (58%) were cracked. Further studies, including FTIR and melt point analysis, were conducted by Ethicon's scientists to determine the cause of the cracking observed in Prof. Guidon's explants. In a report authored by Mr. Burkley on September 30, 1987, he concluded that the Prolene explants had insufficient antioxidants to protect them from oxidation which led to *in vivo* degradation of the Prolene devices.<sup>25</sup> Importantly, Ethicon has not made any changes to Prolene since it was introduced to the market, except that, in 2011, they reduced the amount of Sanatanox (another antioxidant), which could potentially make Prolene more, not less, susceptible to oxidized degradation.<sup>26</sup> Thus, Ethicon's internal studies clearly demonstrate that Ethicon's scientists had concluded that Prolene can degrade while implanted in the human body.

Ethicon subsequently hired an outside consulting firm to resolve the cause of the erosion of its surgical meshes for the pelvic floor. In a June 22, 2011 report, PA Consulting

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<sup>23</sup> Burkley Dep. (5/23/13) 315:8-13.

<sup>24</sup> DEPO.ETH.MESH.00004755

<sup>25</sup> ETH.MESH.12831391 at ETH.MESH.1281392

Group informed Ethicon that, “[p]olypropylene can suffer from degradation following implant... a process which initiates after a few days post implantation in animal studies.”<sup>27</sup>

The consulting report discusses numerous images of polypropylene mesh that show “physical degradation” of the mesh.<sup>28</sup> In addition, in a 2009 presentation, Ethicon Medical Director Piet Hinoul stated that meshes are not biologically inert.<sup>29</sup>

I have personally seen mesh that is broken, cracked, brittle and look different from when it came out of the package. Interestingly, despite years of scientific literature, its own internal dog study, performed by consultants it hired, showing that degradation of mesh occurs, and even despite the fact that Ethicon’s own internal risk assessments include degradation as a known risk, Ethicon’s Instructions for Use (IFU) continues to claim to this day that the mesh in the TVT “is not absorbed, nor is it subject to degradation or weakening by the action of enzymes.”<sup>30</sup> This is not simply inaccurate, but is false and misleading for all of the reasons stated above, including, most importantly, that Ethicon’s own internal documents and testimony from its employees confirm that the mesh degrades.

It is my opinion to a reasonable degree of medical certainty that the mesh used in TVT degrades. The effect of chemical and biological degradation of the TVT Prolene mesh in a woman’s tissues can lead to a greater foreign body reaction, enhanced inflammatory response and excessive scarring, which can lead to severe complications in patients, including the possibility of multiple erosions that can occur throughout one’s lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic

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<sup>26</sup> ETH.MESH.02589032 and ETH.MESH.07192929 (May 18, 2011 PA Consulting Report: Investigating Mesh Erosion in Pelvic Floor Repair and PowerPoint presentations)

<sup>27</sup> ETH.MESH.02589032 and ETH.MESH.07192929 (May 18, 2011 PA Consulting Report: Investigating Mesh Erosion in Pelvic Floor Repair and PowerPoint presentation).

<sup>28</sup> *Id.*

<sup>29</sup> ETH.MESH.01264260 (Presentation, “Prolift+M,” P Hinoul, MD, Ethicon Pelvic Floor Expert’s Meeting – Nederland, Utrecht, May 7, 2009).

dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon's TVT mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

Given the information available in the scientific and medical literature concerning the potential for degradation of polypropylene, it is my opinion to a reasonable degree of medical certainty that Ethicon should have conducted clinically relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene to degrade and if so, what the quantity and quality of the products of degradation would be, whether they would be released into surrounding tissues and/or migrate in the woman's body, what the clinical implications for the woman would be and whether some women's body's would react differently to the mesh and the degradative process and its by-products.

Moreover, Ethicon failed to inform physicians or patients about the potential for degradation of the mesh and the complications that could follow. In fact, Ethicon not only failed to disclose these risks to physicians and patients, it did not accurately describe these significant risks by calling them "transitory" and by putting inaccurate statements about degradation in its IFU. This is information physicians need to know in order to have a fair and proper conversation with their patients about the use of a product. Physicians rely on device manufacturers to inform them of the risks and complications associated with their products instead of downplaying them or inaccurately stating them. By not disclosing this safety information to physicians and their patients, it is my opinion to a reasonable degree of

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<sup>30</sup> May 2015 TVT IFU; ETH.MESH.02340406

medical certainty that Ethicon failed to properly inform physicians and patients about the risks of degradation of Prolene mesh in the TVT. In addition, by failing to inform physicians, Ethicon did not provide them with an opportunity to adequately discuss these risks with their patients.

## **2. Chronic Foreign Body Reaction**

The human body has a natural and fairly predictable “host defense response” to any foreign object placed inside of it. Whether a splinter or a surgical mesh, the human body will send white blood cells to attack the invader and, if the products of inflammation cannot ward off or destroy the invader, including if the invader is anything from bacteria to prosthetic implants, the initial acute inflammatory phase is followed by a chronic inflammatory phase. Therefore, with the placement of something like a permanent surgical mesh in human tissues, there will be a chronic or permanent foreign body reaction to the implant, as well as a chronic inflammatory response by the body.<sup>31</sup> In fact, Ethicon Medical Directors, Piet Hinoul and Charlotte Owens, have both testified that the chronic foreign body reaction created by the body’s response to mesh can cause a severe inflammatory reaction, which can cause chronic pain, nerve entrapment, erosions, dyspareunia and the need for additional surgeries.<sup>32</sup>

Consultants and experts in the field informed Ethicon that there would be chronic tissue reaction to its polypropylene meshes. During a 2006 meeting at one of Ethicon’s facilities, Bernd Klosterhalfen, a pathology consultant expert for Ethicon, informed Ethicon that there

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<sup>31</sup> Klinge, U., et al., *Shrinking of Polypropylene Mesh In Vivo: An Experimental Study in Dogs*, Eur J Surg 1998, 164: 965-969; Klinge, U., *Foreign Body reaction to Meshes Used for the Repair of Abdominal Wall Hernias*, Eur J Surg 1998, 164:951–960; Klosterhalfen, B., *The lightweight and large porous mesh concept for hernia repair*, Expert Rev. Med. Devices 2005, 2(1); Binnebosel M, et al., *Biocompatibility of prosthetic meshes in abdominal surgery*, Semin Immunopathol 2011, 33:235-243; ETH.MESH.03658577 (Biocompatibility of Ultrapro).

<sup>32</sup> Hinoul Dep. (4/5/12) 99:09-25; (4/6/12) 518:14-520:20; (6/26/13) 175:1-176:17; 184:18-22; 328:10-24; Owens Dep. (9/12/2012) 98:11-99:07.

can be a continuing reaction between tissues in the body and mesh for up to 20 years.<sup>33</sup> In addition, during a February 2007 meeting, Ethicon stated that there can be, “[E]xcessive FBR [foreign body reaction]> massive scar plate > more shrinkage.”<sup>34</sup>

Internally, Ethicon’s scientists agreed. Dr. Holste testified that chronic foreign body reactions occurs in Ethicon’s small pore, heavyweight meshes like the Prolene mesh found in TVT.<sup>35</sup> In fact, Dr. Holste testified that Ethicon developed lighter weight, large pore meshes in order to minimize the complications seen with heavyweight meshes like the Prolene used in TVT.<sup>36</sup> Ethicon employee, Christophe Vailhe, testified that there can be an excessive inflammatory reaction or foreign body reaction that would lead to mesh erosion and contraction.<sup>37</sup> Despite its knowledge about the problems associated with chronic foreign body reaction, Ethicon continues to use a heavyweight, small pore mesh in its TVT product.

Contrary to this scientific evidence, Ethicon informed doctors in its IFU that its TVT mesh was “non-reactive with a minimal and transient foreign body reaction,” until the IFU was updated in 2010 to remove the word “transient.”<sup>38</sup> This was despite all of the internal documents and testimony discussed above from Ethicon’s Medical Affairs and Research and Development employees that chronic foreign body reaction occurs in small pore, heavyweight meshes like the Prolene mesh in TVT. Moreover, as one of Ethicon’s lead engineers stated: “the foreign body reaction is not transitory – it doesn’t ever go away, but decreases over time to a minimal level.”<sup>39</sup> That is, it is chronic. I have reviewed numerous pathology reports from my own patients and other physician’s patients and pathology reports reviewed in litigations

<sup>33</sup> ETH.MESH.00870466 (June 6, 2006 Ethicon Expert Meeting Meshes for Pelvic Floor Repair, Norderstedt).

<sup>34</sup> ETH.MESH.01218361 (Ethicon Presentation: “State of Knowledge in ‘mesh shrinkage’-What do we know”).

<sup>35</sup> Holste Dep. (7/29/13) 52:5-55:21.

<sup>36</sup> Holste Dep. (7/29/13) 51:3-53:6.

<sup>37</sup> Vailhe Dep. (6/21/13) 383:8-19.

<sup>38</sup> ETH.MESH.02340406; ETH.MESH.02340531; TVT IFU, May 2015

describing foreign body reactions. Hence, the mesh potentiates a chronic, long-term inflammation. This is contrary to the express language of the TVT IFU up until 2010 and, to this date, the IFU still does not state the foreign body reaction is chronic.

Even before Ethicon launched the TVT with the heavyweight, old construction mesh for sale in the United States. Ethicon knew that Prolene mesh was far from being the ideal material for use in vaginal tissues.<sup>40</sup> However, despite knowing this, Ethicon decided to launch the product for use in repair of anterior prolapse, in order to gain entry into the market before competitors. Ethicon also knew that doctors had expressed fears about rejection and problems with removing the mesh at a later date, fear of infection, concern that the mesh could erode into the bladder or rectum, and concern about the stiffness of the mesh and the risk of the mesh protruding through the vagina. Even knowing of these concerns regarding the use of Prolene mesh in women's vaginal tissues, Ethicon proceeded to launch the TVT with the heavyweight, 1974 old construction Prolene mesh.

For the reasons set forth above, it is my opinion to a reasonable degree of medical certainty that the Prolene polypropylene mesh in the TVT creates a chronic foreign body reaction which can lead to severe complications in patients, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon's TVT mesh (Prolene) is not suitable for its intended application as a permanent prosthetic

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<sup>39</sup> ETH.MESH.00211259.

<sup>40</sup> ETH.MESH.12009027

implant for stress urinary incontinence in women.

Moreover, Ethicon failed to inform physicians or patients about the potential for a severe, chronic foreign body response and the complications that could follow. In fact, not only did Ethicon fail to disclose these risks, it mischaracterized the risks by calling them “transitory” and by putting inaccurate statements about foreign body response in its IFU. This is information physicians need to know in order to have a fair and proper conversation with their patients about the use of a product. Physicians rely on device manufacturers to inform them of the risks and complications associated with its products instead of downplaying them or inaccurately stating them. By not disclosing this safety information to physicians and their patients, it is my opinion to a reasonable degree of medical certainty that Ethicon failed to properly inform physicians and patients about the risks of foreign body response of Prolene mesh in the TVT. In addition, by failing to inform physicians, Ethicon did not provide them with an opportunity to adequately discuss these risks with their patients.

### **3. Infections/Bio-films**

The placement of midurethral slings, including TVT, violates one of the most basic tenets of surgical teachings in that it is the placement of a permanent implant into the patient through a “clean contaminated” surgical field, *i.e.* the vagina, which is not sterile and can never be completely sterilized.

In TVT, the weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing polysaccharide slime (biofilm), which further serves to shield the bacteria from destruction by white blood cells and macrophages.<sup>41</sup> The effect and consequences of

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<sup>41</sup> Osterberg, B., et al., *Effect of Suture Materials on Bacterial Survival in Infected Wounds: An Experimental Study*, Acta. Chir. Scand 1979, 145:7 431-434; Merritt, K., *Factors Influencing Bacterial Adherence to*

biofilm is to increase the foreign body reaction, resulting in chronic infections, chronic inflammation, erosions, and mesh and scar contracture, and was well known to Ethicon, as evidenced by the testimony of Ethicon's Head of Pre-Clinical, Dr. Joerg Holste.<sup>42</sup>

Importantly, the biofilm actually serves as a protection for the bacteria surrounding the mesh fibers against the body's host defense response (white blood cells), which are intended to destroy foreign invaders like bacteria. Thus, the weave induces the creation of a shield against the body's defenses to the bacteria entrained in the woven mesh, inhibiting the body's ability to fight off the infective agents within the mesh. The large surface area promotes wicking of fluids and bacteria which provides a safe haven for bacteria which attach themselves to the mesh during the insertion process.<sup>43</sup> Daniel Burkley testified that reducing surface area could reduce the amount of chronic inflammation.<sup>44</sup> Additionally, the size of the mesh placed equates to a large surface area with many places for bacteria to hide while being protected from host defenses leading to numerous complications.<sup>45</sup>

There have been numerous peer-reviewed journal articles regarding secondary-mesh related infections as well as the dangers of implanting surgical mesh in a clean/contaminated field. Of note, in May of 2013, at the AUA meeting in San Diego, Dr. Shah and his colleagues reported on the "*Bacteriological Analysis of Explanted Transvaginal Meshes*," which included explanted samples of both SUI slings and prolapse meshes. Of the 50 explants examined, 52% of those explanted due to patient complaints' of

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*Biomaterials*, J Biomat Appl 1991, 5:185-203; An, Y., *Concise Review of Mechanisms of Bacterial Adhesion to Biomaterial Surfaces*, J Biomed Mater Res (Appl Biomat) 1998, 43:338-348; The TVM Group: J. Berrocal, et al., *Conceptual advances in the surgical management of genital prolapsed*, J Gynecol Obstet Biol Reprod 2004, 33:577-587.

<sup>42</sup> Holste Dep. (7/30/13) 295:24-298:14, 411:15-414:24.

<sup>43</sup> Klinge, U., et al., *Do Multifilament Alloplastic Meshes Increase the Infection Rate? Analysis of the Polymeric Surface, the Bacteria Adherence, and the In Vivo Consequences in a Rat Model*, J Biomed Mater Res 2002, 63:765-771; Vollebregt, A, et al., *Bacterial Colonisation of Collagen-Coated Polypropylene Vaginal Mesh: Are Additional Intraoperative Sterility Procedures Useful?*, Int Urogyn J 2009, 20:1345-51.

<sup>44</sup> Burkley Dep. (5/22/13) 371.

painful mesh were infused with pathogenic organisms, 20% of those explanted due to vaginal erosions had pathogenic organism, and 83% of those explanted due to urinary tract erosions were contaminated with pathogenic organisms.<sup>46</sup>

When polypropylene particles separate from the surface of the mesh fiber due to degradation, see *infra*, the surface area of the mesh is greatly increased thus providing even greater areas for bacterial adherence to the mesh, more elution of toxic compounds from the polypropylene, and also more of the free toxic polypropylene itself, all of which increases the inflammatory reaction and intensity of the fibrosis.<sup>47</sup> This cracking of the mesh surface also provides safe harbors for infectious bacteria to proliferate.

In his periodic histopathological analyses for Ethicon of its pelvic floor explants, Dr. Klosterhalfen reported to Ethicon that, in virtually 100% of those instances in which mesh had been explanted due to erosions, he found a secondary, mesh-related infection at the tissue/mesh interface.<sup>48</sup> Mesh exposure and erosion cause the fibers to be further exposed to bacteria that will adhere to and colonize on the mesh surface.

Ethicon employees have testified that they were aware of these biofilms forming on the surface of the mesh.<sup>49</sup> However, Ethicon never performed any long-term, clinical studies to determine whether the warnings given them through the peer-reviewed literature and by their own experts and consultants were accurate, namely that mesh-related infections are real; that they cause patient injury in the form mesh erosions and recurrent, late infections; and that the transvaginal implantation through and into the non-sterile, septic vagina is below the standard of care for any surgical technique, especially one used to treat

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<sup>45</sup> Klinge, *supra* n. 26; Vollebregt, *supra* n. 26.

<sup>46</sup> Shah, K., et al., Bacteriological Analysis of Explanted Transvaginal Meshes (Abstract 1144).

<sup>47</sup> Jongebloed, *supra*, n. 1; Sternschuss, G, et al., *Post-Implantation Alterations of Polypropylene in the Human*, J Urol 2012, 188:27-32; Clave, *supra*, at 6.

non-life threatening conditions, such as stress urinary incontinence.

Therefore, it is my opinion to a reasonable degree of medical certainty that the TVT mesh is susceptible to biofilm formation due to the weave of the mesh allowing the infiltration, harboring, and protection of bacterial contaminants; the degraded mesh surface harboring bacteria; the passage through and into a clean/contaminated field; and after exposure/erosion of the mesh into the vagina or other organs, further contamination of the mesh with a multitude of vaginal flora that further increases the risk of harmful and recurrent infections in women. Accordingly, the TVT transvaginal technique, as well as the TVT mesh itself, are not safe for their intended purpose of implantation into a woman's pelvic tissues and can lead to severe complications in patients, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon's TVT mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

Finally, Ethicon's claims in its IFU that the TVT mesh may "potentiate infection" are misleading, at best. If, by the intentionally ambiguous term, "potentiate," Ethicon means "cause," then this is true for all of the reasons stated above. If by "potentiate," Ethicon means "exacerbate an existing infection," then the statement is misleading at best. Ethicon failed to warn physicians and patients that a slimy, protective biofilm could form on the mesh

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<sup>48</sup> ETH.MESH. 00006636.

<sup>49</sup> Holste Dep. (7/30/13) 283:19-284:5.

leading to painful erosions, recurrent, late infections and the need for mesh removal. The TVT IFU contrasts sharply with the PROLENE IFU on this issue. The PROLENE IFU states as follows: PROLENE Mesh in contaminated wounds should be used with the understanding that subsequent infection may require removal of the material.<sup>50</sup>

Ethicon did not to include this risk, despite that unlike hernia mesh, TVT mesh is being implanted through a contaminated environment – the vagina. By failing to include this risk, Ethicon did not adequately warn physicians about these important risks, nor by extension, provide surgeons with an opportunity to discuss these risks with their patients.

#### **4. Pore Size and Fibrotic Bridging**

Fibrotic bridging occurs when the fibers surrounding the pores of the mesh are too close together to allow the tissue in the pore enough room to recover from the trauma of tissue damage due to implanting a surgical prosthetic device. Pores that are large enough for good, newly-vascularized tissue tend to be filled with fatty tissue versus small pores that become filled with scarred or fibrotic tissue. In those instances, the scar forms across the pores or “bridges” from one side of the pore to the other. This can occur either due to the granulomas around the mesh fibers joining together or due to densely-formed fibroblasts between these granulomas. Either way, such bridging can lead to the creation of a rigid, scar plate that can encapsulate the mesh with scar tissue. Simply put, small mesh pores that cause fibrotic bridging turn the mesh into a solid sheet of scar tissue and there is no space or room for tissue to grow into the mesh, which is the intended purpose of the mesh. The fibrotic bridging and scar plate prevents tissue in-growth and causes complications, including, among other things, pain with the rigid mesh, shrinkage or contraction of the mesh, erosions due to mechanical

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<sup>50</sup> ETH.MESH.02342102.

irritation in the tissue of a rigid, scar- plated mesh, nerve entrapment, chronic pain and dyspareunia.

This concept is best illustrated by a DVD produced by Ethicon which features an Ethicon consultant, Dr. Todd Heniford, talking about a heavyweight, small pore mesh called Marlex used for hernia repairs.<sup>51</sup> The Prolene mesh used in TVT is of heavyweight, small pore construction and, in fact, is even heavier than Marlex. Ethicon Scientists have acknowledged that the Marlex mesh in the video is similar to the Prolene in TVT in that is heavy weight small pore mesh.<sup>52</sup> Ethicon has also relied on the works of Dr. Heniford relating to lightweight mesh and cited to his works in their marketing materials and professional educational materials for pelvic mesh products. Moreover, Ethicon relied on science and information regarding hernia meshes to claim the safety and efficacy of their pelvic mesh products to regulatory bodies. At least one medical director at Ethicon, Dr. Thomas Divilio, has described the work done by Dr. Heniford and others as “material science” that would apply to both hernia and pelvic mesh products. In my opinion this the video, as well as other science and information regarding hernia meshes and other pelvic meshes of particular relevance when discussing the TVT mesh as Ethicon chose to move to large pore, light weight meshes in these areas, but not for TVT.

In the video, Dr. Heniford talks about the dangers of heavy weight, small pore meshes.<sup>53</sup> In fact, Dr. Heniford states, “there is no excuse for using heavy weight, small pore

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<sup>51</sup> Heniford, B.T., 2007, *The benefits of lightweight meshes in Ventral Hernia Repair in Ventral Hernia Repair*, Video produced by Ethicon.

<sup>52</sup> ETH.MESH.05918776 (5/04/04 Email from Schiaparelli, Jill, Strategic Grown Subject: Marlex Experience); Batke Dep. (8/01/13) 87:12 - 88:10, 113:3-114:3, 257:23-259:13; Holste Dep (7/29/13) 51:3-53:6, 55:22-57:4; Vailhe Dep. (6/20/13) 182:2 185:5.

<sup>53</sup> Heniford Video, supra, n. 46.

meshes in the human body.”<sup>54</sup> I have explanted numerous TVT and TVT meshes and have witnessed meshes with extensive scar plating and mesh encapsulation similar to the hardened/stiffened mesh viewed in the Heniford video. In numerous emails, Ethicon employees discussed concerns regarding fibrotic bridging.<sup>55</sup> They have testified that the heavy weight, small pore type of mesh in the TVT can lead to an increased risk of foreign body reaction, contraction of the mesh, nerve entrapment, erosions and chronic pelvic pain.<sup>56</sup>

In other emails, when discussing these concepts, Ethicon’s World Wide Marketing Director for General Surgery, Marty Chomiak, states that “... we want to avoid ‘bridging’, therefore we think large pores are better than small . . .”<sup>57</sup> Ethicon also had information and scientific knowledge regarding superior mesh designs to prevent fibrotic bridging and scar plating. Specifically, Ethicon also had scientific knowledge that light weight, large pore mesh could decrease the likelihood of foreign body reaction, fibrotic bridging and scar plating.<sup>58</sup>

Despite having clinical knowledge of the importance of pore size to successful outcomes, and dozens of emails about the importance of pore size, Ethicon’s person most knowledgeable about pore size testified that Ethicon does not manufacture its mesh to a specific pore size. Dan Smith testified as follows:

Q: Does Ethicon have a validated test method to determine the pore size of its TVT mesh?

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<sup>54</sup> *Id.*

<sup>55</sup> ETH.MESH.04037600 (Innovations in mesh development); ETH.MESH.05920616 (7/20/07 ; Emails from Chomiak, M. to Batke, B., et al. re Defining light weight mesh); ETH.MESH.05585033 (Boris Batke Presentation – Project Edelweis – Ultrapro); ETH.MESH.05446127 (3/13/2006 Emails from Holste, J. to Engel, D., et al re Mesh and Tissue Contraction in Animal – “Shrinking Meshes?”); ETH.MESH.05475773 (2/09/2007 Boris Batke, Ethicon R&D, Presentation: *The (clinical) argument of lightweight mesh in abdominal surgery*); ETH.MESH.04015102 (3/1/12 Email from Batke, Boris to Mayes, C. re AGES Pelvic Floor Conference-Gala Dinner Invitation); ETH.MESH.04037600 (3/15/12 Boris, B. PowerPoint Presentation, *Innovations in Mesh Development*, Melbourne AGES 2012).

<sup>56</sup> Batke Dep. (8/1/13) 87:12-88:10, 113:3-114:3, 257:23-259:13; Holste Dep. (7/29/13) 51:3-53:6, 55:22-57:4; Vailhe Dep. (6/20/13) 182:2-185:5.

<sup>57</sup> ETH.MESH.05920616 (7/20/07 Email from Chomiak, M. re Defining Light Weight Mesh).

<sup>58</sup> Batke Dep. (8/1/13) 87:12-88:10, 113:3-114:3, 257:23-259:13; Holste (7/29/13) 51:3 - 53:6, 55:22 - 57:4; Vailhe Dep. (6/20/13) 182:2-185:5.

- A: We determine the pore size by courses and wales and that is how it's done. So the courses and wale count is a validated test method.
- Q: And I'm talking about pore size. Does Ethicon have a validated test method to determine its pore size for its mesh?
- A: The construction of the mesh is -- does not have a pore size requirement.<sup>59</sup>

In fact, Ethicon does not even have a test to measure the pore size of its mesh. Dan Smith testified:

- Q. Mr. Smith, does Ethicon have a validated test to describe the pore size of its TVT meshes microns? Yes or no.
- A. No....<sup>60</sup>

Despite this information that it did not measure pore size or manufacture its mesh to a specific requirement, Ethicon repeatedly stated in advertising and marketing materials that its mesh was "large pore." For example, in one brochure, Ethicon promotes the mesh used in the TVT family of products (including TVT) as the "Largest pore size" of any of its competitors, listing the size as 1379 um.<sup>61</sup> However, given that Ethicon has no verified methodology to measure pore size, Ethicon had no scientific basis upon which to base these statements. In fact, in internal documents, Ethicon scientists described PROLENE mesh as small pore: "Standard Mesh PROLENE small pores area weight 105 g/m2."<sup>62</sup> One Ethicon Engineer measured a mesh and determined that there were two pore sizes in the mesh, a "major" and "minor" pore. "There are two distinct pore sizes in the PROLENE 6 mil mesh (TVT). The major pore is about 1176 um.... The minor pore is about 295 um."<sup>63</sup> Certainly, neither of these pores was 1379 um, and the minor pore was substantially smaller.

In addition, the pore size of a mesh can change when the mesh is put under stress such

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<sup>59</sup> Smith Dep. (2-3-14) 729:1 to 729:12.

<sup>60</sup> Smith Dep. (2-3-14) 779:5 to 779:8.

<sup>61</sup> ETH.MESH.00349508 at 9510.

<sup>62</sup> ETH.MESH.04941016.

<sup>63</sup> ETH.MESH.00584175 (Ex. T-3583); ETH.MESH.00584179 (Ex. T-3581).

as when a sheath is removed or the mesh is tensioned. Dan Smith agreed that these stresses can make an effective pore size smaller than 1 mm.

- Q. You would agree, Mr. Smith, that if the measurement across the pores we're looking at here -- let's assume you measure across one of those pores and let's say it's more -- let's say it's 1 millimeter across hypothetically. If a load is put on the mesh and it changes the pore size, that pore could be, after a load is put on it, under 1 millimeter; correct?
- A: It's possible depending on the load.<sup>64</sup>

Ethicon engineer Christophe Vaihle testified that “excessive tension on the mesh would lead to the decrease in pore size that can lead to poor tissue integration . . . .”<sup>65</sup> Ethicon has done nothing to change the mesh and continues to promote and sell the product with the same, heavy weight, thick filament “Old Construction 6 mil” mesh that they have been selling since 1974 (Prolene), despite what Ethicon considers to be “revolutionary” advancements in polypropylene mesh design that it brought to other pelvic floor polypropylene mesh products.<sup>66</sup>

In summary, for the reasons set forth above, it is my opinion to a reasonable degree of medical certainty that the Prolene polypropylene mesh in the TVT causes fibrotic bridging in the body, resulting in an increased inflammatory response leading to a multitude of injuries, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, dyspareunia that can be chronic, nerve injury, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon's TVT mesh

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<sup>64</sup> Smith Dep. (2/3/2014) 816:5 to 816:15.

<sup>65</sup> Vailhe Dep., (6/20/13) 224:10-226:21.

<sup>66</sup> ETH.MESH.03905968; *see also* Prolift +M CER (“As the mass of a mesh implant is reduced and the pore size is increased, the surface area exposed to the host is reduced, and the foreign body reaction to the implant is reduced.”).

(Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

Moreover, Ethicon did not inform physicians and patients that its mesh was susceptible to fibrotic bridging. Ethicon failed to warn physicians and patients that fibrotic bridging could occur leading to painful erosions, recurrent, late infections, nerve injury and the need for mesh removal. By failing to do so, Ethicon did not adequately warn physicians about these important risks, nor by extension, provide surgeons with an opportunity adequately to discuss these risks with their patients.

### **5. Mesh Contracture/Shrinkage**

Mesh contracture or shrinkage is an event that takes place after the implantation of mesh and relates to the wound healing process that occurs after the surgical trauma of implanting a foreign body made of polypropylene in the sensitive tissues of the vagina and pelvis. By 1998, polypropylene mesh was known to contract or shrink 30-50%.<sup>67</sup> These findings were later confirmed in numerous papers, such as those by W. Cobb and his colleagues – one of whom was Dr. Henniford (referenced above).<sup>68</sup> This also showed that heavier weight meshes like TVT led to greater amounts of contraction. The works of Cobb and Klinge/Klosterhalfen have been referenced in numerous Ethicon documents. Contraction or shrinkage has been shown to draw nerves close to the midurethral sling mesh both in the transobturator application<sup>69</sup> and for retropubic application.<sup>70</sup> Furthermore, contraction or

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<sup>67</sup> Klinge, U, *Shrinking of Polypropylen Mesh in Vivo: An Experimental Study in Dogs*, Eur J Surg 1998, 164:965-969.

<sup>68</sup> Cobb, W., et al., *The Argument for Lightweight Polypropylene Mesh in Hernia Repair*, Surgical Innovation 2005, 12(1):T1-T7.

<sup>69</sup> Corona, R., et al., *Tension-free Vaginal Tapes and Pelvic Nerve Neuropathy*, J Min Invas Gynecol 2008, 15:3 262-267; Parnell, B.A., et al., *Genitofemoral and Perineal Neuralgia after Transobturator Midurethral Sling*, Obstet.

Gynecol 2012, 119:428-431; Jacquetin, B, *Complications of Vaginal Mesh: Our Experience*, Intl Urogyn J, 2009, 20:893-6; Tunn, R, *Sonomorphological Evaluation of Polypropylene Mesh Implants After Vaginal Mesh Repair in*

shrinkage is closely related to the pore size and weight of the mesh. Small pore, heavy weight mesh leads to fibrotic bridging which leads to scar plates, mesh encapsulation and shrinkage or contraction of the mesh, which is compounded by the shrinkage effect associated with the normal wound healing process already occurring in the tissue.

This phenomenon of shrinkage and its relation to the design of the pores as well as the consequences to the patient were illustrated in an email by Ethicon Scientist Joerge Holste in a March 13, 2006 email discussing a paper he authored entitled “Shrinking Meshes?”<sup>71</sup> In his email, Dr. Holste states “this was our scientific statement on mesh shrinkage: Basically, small pores, heavy weight meshes induce more fibrotic bridging tissue reaction causing more mesh shrinkage during maturation of the collagenous tissue. See my presentation about biocompatibility.”<sup>72</sup> In addition, in a presentation by Boris Batke, Associate Director R&D, he states heavier-weight polypropylene mesh results in mesh contraction of 33%.<sup>73</sup> In an email dated November of 2002, related to a discussion of mesh used in a TVT product, Axel Arnaud, one of Ethicon’s medical directors, used 30% shrinkage of the mesh as a “rule of thumb.”<sup>74</sup> At an Ethicon expert meeting in Norderstedt, Germany in 2007, an Ethicon employee presented a PowerPoint entitled “Factors Related to Mesh Shrinkage” in which all of these issues were clearly laid out.<sup>75</sup>

Mesh shrinkage was known by Ethicon as early as 1998 in published work by Ethicon’s

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*Women with Cystocele or Rectocele*, Ultrasound Obstetrics Gynecol 2007, 29:449-452.

<sup>70</sup> Heise, C.P., et al., *Mesh Inguinodynia: A New Clinical Syndrome After Inguinal Herniorrhaphy?*, J Am Coll Surg.

<sup>71</sup> ETH.MESH 05446127, *supra*, n. 34.

<sup>72</sup> *Id.*

<sup>73</sup> ETH.MESH 05479717 (3/1/11 Boris Batke, Ethicon Associate Director R&D, Presentation: Ethicon Polypropylene Mesh Technology).

<sup>74</sup> ETH.MESH 03917375.

<sup>75</sup> ETH.MESH. 02017152 (Nordestadt Expert’s meeting 2007); ETH.MESH.01782867 (Factors Related to Mesh Shrinking).

then consultants, Uwe Klinge and Bernd Klosterhalfen.<sup>76</sup> They noted in these early papers that all polypropylene meshes shrink 30-50%. This was restated in later works by W Cobb and his colleagues<sup>77</sup>--one of which was Dr. Heniford (referenced above). The words of Cobb and Klinge/Klosterhalfen have been referenced in numerous Ethicon documents and thus, Ethicon was well aware of these findings regarding the shrinkage or contraction of polypropylene meshes in vivo. Ethicon was further aware that heavier weight meshes led to greater amounts of contraction. And, notably, Ethicon equated the tissue reaction in the abdomen to heavyweight mesh to the tissue reaction in the pelvis to heavyweight mesh in marketing materials, professional educational materials and regulatory materials.

It is my opinion to a reasonable degree of medical certainty that as a result of work with internal and external experts and consultants in the late 1990s, multiple internal documents and articles, and the scientific literature as a whole, that Prolene mesh used in TVT not only could, but would shrink and contract, and that this shrinkage could lead to painful complications in women implanted with TVT, such as multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, nerve injury, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others.

As a result, the polypropylene in Ethicon's TVT mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women, and Ethicon failed to warn physicians and patients of the possibility of shrinkage and

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<sup>76</sup> Klinge U, Klosterhalfen B, Muller M, Ottinger A, Schumpelick V. Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs. Eur J Surg. 1998; 164: 965-969

contraction and the adverse outcomes that could occur as a result.

**6. Fraying, Particle Loss, Roping and Curling, Deformation and Loss of Pore Size**

Ethicon designed the TVT mesh such that, when stress was put on the mesh, particles would separate from the mesh – this was called fraying or linting.<sup>78</sup> One of Ethicon’s engineers described this as a “defect” that resulted from the method of cutting the mesh: “The mesh frayed is the reverse defect of the mesh features (elasticity of the mesh is one of the commercial arguments to market the TVT)... [T]he root cause of this phenomenon are known: the way to cut the mesh (blade cutting). If we change the way to cut the mesh (ultrasonic cutting or laser cutting) it seems we can limit the mesh frayed defect significantly....”<sup>79</sup>

As early as 2000, Ethicon’s engineers documented that particles from TVT Prolene mesh fell into women’s tissues as a result of the tape edges being damaged during sheath removal.<sup>80</sup> In April 2001, Dr. Alex Wang, “one of the most experienced TVT users in the world,” reported problems with frayed mesh and uneven tape width.<sup>81</sup> Although the issue was described as “serious” and as requiring “urgent attention and solution,” Ethicon Medical Director, Dr. Martin Weisberg, simply concluded that the deformity in the mesh would be unlikely to have any clinical significance. Dr. Weisberg testified that although he did not actually know whether frayed mesh leading to particle loss would have clinical implications,

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<sup>77</sup> ETH.MESH.07455220.

<sup>78</sup> Weisberg Dep. (5/31/13) 461:7-462:3 (“Q. So engineers within the company knew that fraying of the product was inherent in the design? A. Yes.”).

<sup>79</sup> ETH.MESH.01813975 at 2 (Ex. 3160/3587).

<sup>80</sup> ETH.MESH.01317515 (7/12/00 Preventia TVT-2 Risk Analysis Procedure/Tensioning Frayed Mesh/Particle Loss). at 7523.

<sup>81</sup> ETH.MESH.03905472 (6/4/01 Emails from Wang, A. re TVT Recommendation for Ethicon Study of

he does not recall whether he or anyone else at Ethicon studied the issue.<sup>82</sup> Just a few months later, however, Ethicon received a complaint by an experienced surgeon regarding a patient who experienced vaginal wall erosion following a TVT procedure which was first noted by her husband during intercourse.

According to the surgeon, “the tape appeared frayed and tiny fibers were protruding through the vaginal wall.”<sup>83</sup> In November 2003, Dr. Weisberg reported that there had been a total of 58 complaints of fraying with TVT since introduction of the device in 2000. He observed that the following occurs when the mesh frays: “[T]he mesh elongates in places; the mesh narrows in places; and small particles of Prolene might break off ... and that [s]tretching of the mesh increases the probability of fraying.”<sup>84</sup> Once again, however, Dr. Weisberg concluded that “since fraying does not affect the safety and efficacy of the TVT device, it has been determined not to pursue any corrective actions at this time.”<sup>85</sup> Dr. Weisberg confirmed during his deposition that no corrective action was taken and, although he did not know whether Prolene particles could elicit a chronic foreign body response, he does not recall whether he or anyone else at Ethicon investigated the issue.<sup>86</sup>

In 2004, Ethicon continued to receive complaints from surgeons about fraying and “brittle” mesh and particles falling into the operating field.<sup>87</sup> One of the company’s “most urgent customers,” Swiss surgeon Dr. J. Eberhard, wrote the following: “Already at the operation it is embarrassing to see how the tape is crumbling. But it gets worse if there is

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Fraying/Particle Loss).

<sup>82</sup> Weisberg Dep. (5/31/13) 469:23-470:16.

<sup>83</sup> ETH.MESH.02621559 at 2276 (Ethicon Issue Report TVT Retropubic 2001 Open Date Between 01- Jan-2001 and 31-Dec-2001).

<sup>84</sup> ETH.MESH.00541379 (11/18/03 Memo from Weisberg re Mesh Fraying for TVT Devices Inadequate Testing).

<sup>85</sup> *Id.*

<sup>86</sup> Weisberg Dep. (5/31/13) 469:23-470:16.

<sup>87</sup> ETH.MESH.00863391 at 3392 (2/27/04 Emails from Smith, D. re 2 TVT Complaints Concerning Allegedly Brittle Mesh).

stretch on the tape.... I can't understand that no one will solve that problem for such a long time. As the latest, as the tape has becoming blue, everyone has realized that the quality of the tape is terrible.”<sup>88</sup>

Dan Smith, the Lead Engineer on TVT lamented the particle loss that was revealed when the mesh was dyed blue: “This is not going away anytime soon and competition will have a field day, major damage control offensive needs to start to educate reps and surgeons UPFRONT that they will see BLUE shit and it is OK.”<sup>89</sup> Indeed in November 2004, one of the “top 3 complaints” included “Mesh frayed.”<sup>90</sup> Once again, however, Ethicon decided to take no corrective action.<sup>91</sup> Instead, sales representatives were instructed to reassure their doctors that, “Prolene is proven to be inert,” the “particles will not cause any problem,” and to “be proactive” because “the competition will try to target this!”<sup>92</sup> Physicians were told the particles are “non- reactive” and that fraying does not affect the safety or efficacy of the device.<sup>93</sup> In fact, it has consistently been Ethicon’s position that frayed mesh and resulting particle loss as well as roping, curling and deformation of the mesh do not create a safety risk and have no clinical significance.<sup>94</sup>

However, as noted above, Ethicon never tested whether the particles would cause pain in women.<sup>95</sup> Moreover, Ethicon never specifically tested whether the particles, or frayed,

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<sup>88</sup> ETH.MESH.02180833 (11/12/04 Letter from Prof. Dr. Eberhard (translated)); ETH.MESH.02180828 (11/12/04 Telefax from Sibyll, B. re Prof. Dr. Eberhard).

<sup>89</sup> ETH.MESH.00863391.

<sup>90</sup> ETH.MESH.01813975 (Ex. T-3160 / T-3587).

<sup>91</sup> ETH.MESH.02180826 (11/12/04 Email from Menneret, D. re Mesh Fraying: Dr. Eberhard Letter).

<sup>92</sup> ETH.MESH.00865322 (3/2/04 Email from Bell, S., Ethicon Marketing Director Europe to Sales & Marketing Team re Reminder on Blue Mesh – Frayed Mesh/Particle Loss).

<sup>93</sup> ETH.MESH.03535750 (10/12/2005 Hunsicker, K., Ethicon Clinical Operations Regional Manager, Presentation: *Investigator Initiated Study Process – Inadequate Testing*).

<sup>94</sup> ETH.MESH.00541379, *supra*, n. 58; ETH.MESH.00858252 (2004 Memo from London Brown, A. re Mechanical Cut v. Laser Cut Mesh Rationale).

<sup>95</sup> Trial Testimony of Piet Hinoul, *Batiste v. Ethicon*, page 26-28.

curled shrunken and deformed mesh, would cause pain when in close proximity to the pelvic and vaginal nerve bundle and muscles. An independent investigator, Dr. Pariente, did and published a study that concluded that “the very high particle shedding for both Sparc (AMS) and TVT (Ethicon) may be of significant long term clinical concern in some quarters.”<sup>96</sup> In addition, Ethicon collected data from physicians who informed Ethicon that particles could, indeed, cause pain and dyspareunia.<sup>97</sup> Moreover, Ethicon medical director Piet Hinoul testified the particles that fall off the mesh create inflammation and inflammation can cause pain.<sup>98</sup> Although Ethicon claims that its own internal testing shows approximately 1% particle loss with TVT,<sup>99</sup> Dr. Pariente’s study demonstrated TVT particle loss as high as 8.5% - 10 times higher than most of its competitors.<sup>100</sup> In addition, Ethicon’s April 2006 Clinical Expert Report on Laser Cut Mesh suggested there was a decrease in particle loss with laser cut mesh and this “decrease would lead to less non-functioning material left in the tissues.”<sup>101</sup> It cannot be disputed that the greater the nonfunctioning material left in a patient’s tissues, the greater the surface area of polypropylene the patient is exposed to, and the greater the inflammatory responses and the greater the foreign body response. As discussed above, the long term consequences of this chronic foreign body reaction and inflammatory response can be, among other things, chronic pain, lifelong risk of erosions, dyspareunia and failure of the device. If the individual flakes work their way through the vaginal mucosa, this can lead to dyspareunia and/or painful intercourse for the partner as noted in the complaint received by Ethicon back in

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<sup>96</sup> ETH.MESH.01221055 (Pariente, J-L, *An independent biomechanical evaluation of commercially available suburethral slings*, Issues in Women’s Health 2003).

<sup>97</sup> ETH.MESH.05644163 at 4166 (Dr. Hilton, one of Ethicon’s principal investigators in the TVT v. Burch trial, informed Ethicon that: “The small particles migrate and cause pain during intercourse.”).

<sup>98</sup> Trial Testimony of Piet Hinoul, *Batiste v. Ethicon*, page 26-28.

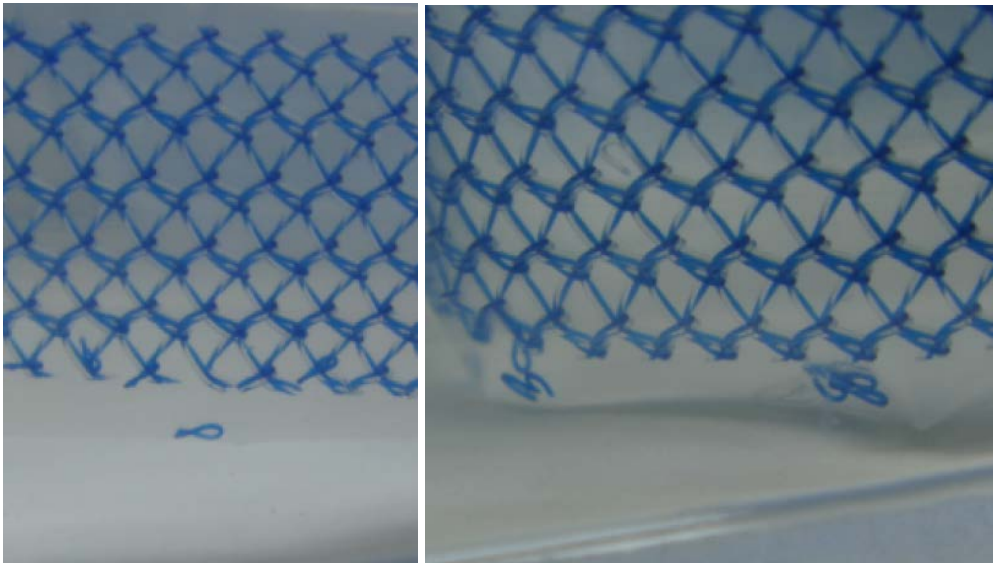
<sup>99</sup> ETH.MESH.000585802; ETH.MESH.00585842; ETH.MESH.00585823 06/27/06 (Email from Kammerer, G. re GY: \*\*\*URGENT\*\*\* French STANDARD ON TVT & MESHES (COMMENTS REQUIRED)).

<sup>100</sup> ETH.MESH.01221055, *supra*, n. 67; ETH.MESH.00585842 (6/12/06 Email from Kammerer, G. re TVT LCM –

<sup>101</sup> ETH.MESH.00167104 at 7109.

2001 referenced above. The larger the surface area the greater the risk associated with vaginal mesh. Finally, detached flakes of polypropylene may migrate into the vasculature or lymphatics and cause problems remote from the pelvis. For these reasons, Ethicon should have used a mesh without a fraying and particle loss defect when selling its TVT for permanent implant in a woman's vaginal tissues.

Ethicon continued to receive complaints related to particle loss from the mechanically cut mesh in the TVT. In 2010, customers complained that they were seeing pieces of mesh in the unopened packages. Ethicon employees initially responded that "No, this is not nor do we recommend using the product." Pictures from Ethicon's complaint file reveal particles of the mesh that have begun to break off from the mesh inside the package.<sup>102</sup>



Nine packages with particles of loose mesh were returned to Ethicon for analysis. I have requested to examine these products, but have been told that Ethicon has discarded these

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<sup>102</sup> ETH.MESH.13204508.

products.<sup>103</sup> Ethicon employees later reversed their position on the mesh particles stating that: “mesh particles of this size are common with the manual cutting process and are within our specifications. The product is safe to use.”<sup>104</sup> This conclusion seems to be at odds with internal manufacturing documents indicating that nearly 2,000 TVT and other mesh products were rejected because of foreign matter in the product or packaging during the month of March, 2010 alone at Ethicon’s Neuchatel manufacturing facility.<sup>105</sup> Ethicon’s conclusion that the products were safe to use does not appear to be a result of any scientific or engineering study of the returned products, but rather the conclusion of Ethicon Medical Director David Robinson that “...the possibility for the tiny tape fragments observed... ... to cause adverse consequence in a patient... ... should be considered remote. The presence of tiny tape fragments in the product package is not expected to change the product safety profile.”<sup>106</sup> It is my opinion to a reasonable degree of medical certainty that this conclusion is incorrect and not supported by any study or clinical evidence gathered by Ethicon. In fact this conclusion is belied by the fact that Ethicon told the same physicians who complained about the particles that they may wish to consider TVT mesh manufactured with a laser cutting process that does not result in tiny mesh particles within the package.<sup>107</sup> Because of dangers associated with loose particles, fraying and deformed mesh, described more fully below, the mesh from this TVT mesh posed unreasonable dangers to women and Ethicon should have never allowed the mechanically cut mesh in the TVT to be offered for sale for implantation in women.

In addition to fraying and particle loss, the mechanically cut meshes used in TVT has

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<sup>103</sup> Letter from Ben Watson to Andrew Faes, April 16, 2015; Letter from Andrew Faes to Ben Watson, March 25, 2015.

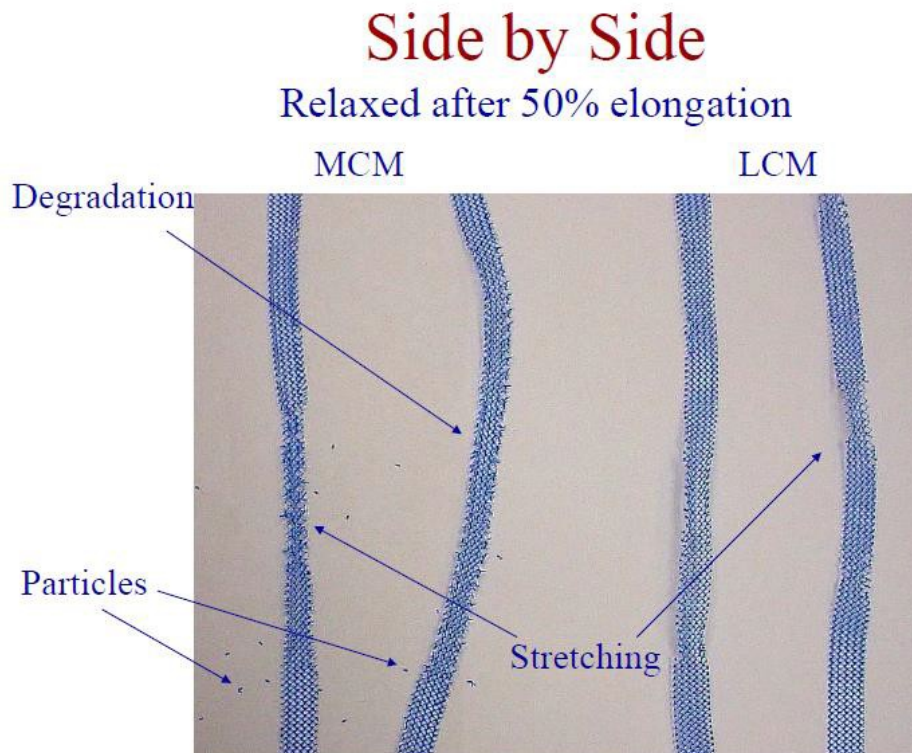
<sup>104</sup> ETH.MESH.13226457.

<sup>105</sup> ETH.MESH.13907354-55.

<sup>106</sup> ETH.MESH.04101014.

<sup>107</sup> ETH.MESH.13226457.

also been shown to rope, curl and deform when under tension. In 2006, an Ethicon Engineer, Gene Kammerer, made a presentation that clearly showed each of these defects in the mechanically cut mesh. These photos clearly show particle loss, fraying, degradation, roping and deformation when the mechanical cut mesh was stretched and compared to TVT Laser Cut.<sup>108</sup>



As noted these photos show mesh after 50% elongation. I have read depositions of Ethicon personnel claiming this is not a realistic elongation seen with mesh. However, Ethicon's engineer who took the photos, Gene Kammerer, explained that he had experienced it himself in testing:

The link between the elongation percent, not force, and the integrity of the mesh is this. During the operative procedure as the surgeon removes the protective sheath from the mesh, the mesh stretches or elongates. It is my experience, after viewing many surgical procedures and performing numerous procedures on cadavers myself, that the mesh stretches approximately 50% at

<sup>108</sup> ETH.MESH.08334245.

the maximum. There is also additional stretching that occurs if the surgeon elects to do an adjustment on the position of the mesh under the urethra. It is these two occurrences which produce the majority of the particle loss and loss of the integrity of the construction of the mesh.<sup>109</sup>

Again, Ethicon claimed that these problems with the mesh did not have any clinical significance despite the fact that surgeons were complaining.<sup>110</sup> However, Ethicon's own internal documents demonstrate that this is not true. According to Ethicon's Failure Modes documents, the loss of pore size due to mesh narrowing or deformation can lead to urinary retention or erosion. Ethicon's own dFMEA from 2006 shows that the hazards of curling/roping, frayed edges and inadequate pore size of mesh can lead to the harms of erosion, recurrence, and pain.<sup>111</sup>

When discussing the dFMEA for Laser Cut Mesh, Former Medical Director, David Robinson, agreed that pore size of both the Laser Cut and Mechanically Cut mesh "[c]ould reduce, the tissue might not encapsulate . . . the tissue might not grow through the mesh. It can become encapsulated and then it could cause . . . a rejection of the mesh."<sup>112</sup> And, Dr. Robinson testified that rejection of the mesh can lead to erosion.<sup>113</sup> These changes in the mesh may lead to erosion or pain for women with the deformed mesh implanted in their bodies. Further, according to Ethicon, this curling, roping or narrowing of the mesh may also cause urinary retention in addition to erosion and pain.<sup>114</sup>

In fact, I have witnessed the same type of roping and narrowing of TVT when I placed them myself. I see the deformed and roped mesh when I remove them. This localized pressure under the urethra leads to complications like, among others, urinary retention, chronic pain,

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<sup>109</sup> ETH.MESH.00584811.

<sup>110</sup> ETH.MESH 00440005; ETH.MESH 00302390 (TVT-Base & TVT Review for Laser Cut Mesh (LCM) Risk Analysis).

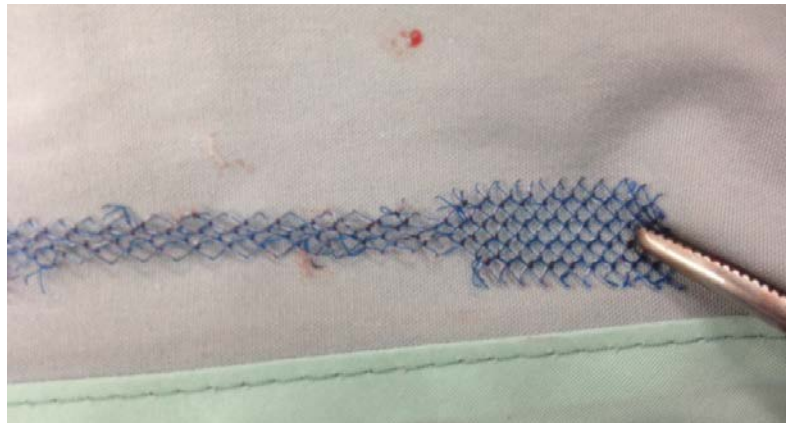
<sup>111</sup> ETH.MESH.01218019.

<sup>112</sup> Robinson Dep. (9/11/13) 1070:23-1072:25.

dyspareunia and erosions. In addition, I have reviewed Ethicon TVT training videos that show the exact problem discussed about related to deformation and roping of the “tape” under the urethra.<sup>115</sup> Finally, according to Ethicon’s Dan Lamont, it chose to continue to sell “mechanically cut mesh despite knowing that it had the potential for degradation, particles floating around in women’s bodies, stretching, and roping . . .”<sup>116</sup> Lamont admitted that the fraying of the mesh was a “defect” of the mesh.<sup>117</sup>

Not surprisingly, Ethicon continues to receive complaints related to the mechanical cut mesh used in TVT fraying, roping and curling. Recently, the highest volume user of TVT products in Canada, Dr. Kenny Maslow, complained to Ethicon that the mesh used in TVT would fray down to a thin fiber even with “very little tension applied to the sling.”<sup>118</sup>

Dr. Maslow included a picture of the frayed mesh used in TVT when he reported the issue to Ethicon.




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<sup>113</sup> *Id.*

<sup>114</sup> Robinson Dep. (9/11/13) 1079:3-4-1081; 1081:9-13; 1083:8-18; ETH.MESH.01218019.

<sup>115</sup> ETH.MESH.PM.000004 (TVT Retropubic Implantation Video).

<sup>116</sup> Lamont Dep. (9/11/13) 30:18-24.

<sup>117</sup> Lamont Dep. 9/11/13) 15:16-16:10.

<sup>118</sup> ETH.MESH.12910023.

Another feature of mechanically cut mesh is its sharp edges as shown on this photo:<sup>119</sup>



While Ethicon states that these sharp edges are part of the intended “velcro” effect of mesh, it was a feature about which Ethicon had received complaints tied to injuries and erosions. For example, during on market research test with physicians, it was reported:

The surgeon felt that the MCM strips was elastic but with "hairs" on the edges and that it scratched with abrasive texture scraping (like the Scotch -Brite™ pads), furthermore a lot of particles were released and a rope/string effect could occurred if an excessive force was applied.<sup>120</sup>

In fact, when one agency recognized a spike in erosions, it inquired whether this was a result of “the cut ends of the tape appear to be sharper and more likely to cut tissue.”<sup>121</sup> A sentiment shared by some physicians and reported to Ethicon:

Basically, he thinks that erosions due to the TVT mesh are underestimated in reports. The reason is that in order to recognize them, a very careful vaginal examination is needed. Most of the time, a "hidden" erosion is asymptomatic and neither the patients nor their sexual partner if any complain. But it might happen that a patient may complain. He believes that erosion are due to the sharp edges of the mesh. He wanted to suggest that we add to the mesh edges a

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<sup>119</sup> ETH.MESH.09656795.

<sup>120</sup> ETH.MESH.06696589.

<sup>121</sup> ETH.MESH.00330760.

kind of seam that would help preventing erosion.<sup>122</sup>

Dr. Axel Arnaud responded that Ethicon did not want to modify its mesh (even if it caused erosions) because Ethicon did not want to lose the marketing edge of using the Ulmsten/Nilsson data. He wrote:

I also indicated that we want to be very careful with any modifications of our tape since a change in the mesh would obsolete all the long term clinical results we have about the procedure.<sup>123</sup>

However, the market pressure on Ethicon to create a laser cut mesh without particle loss, roping and deformation became very strong. Paula Evans, Gynecare European Marketing Manager, described the situation as “France is in a recovery mode, Germany is hemorrhaging business ... Without laser cut, there is the real risk that more business will be lost.”(sic)).<sup>124</sup> Hence, the laser cut mesh project went forward presumably in an effort to address the chronic problems with particle loss, fraying, sharp edges and elongation seen with mechanically cut mesh.<sup>125</sup>

During early development of laser cut, Ethicon acknowledged that mechanical cut mesh and laser cut mesh were two separate mesh products and to imply otherwise would be misleading. In December 2005, Kevin Mahar described the marketing strategy “...KEEP selling regular TVT (the ‘Colonel’s Original Recipe’) to those customers that want/love it...and KEEP going forward with 8 years of data, etc with the original recipe ... We do not mislead them that this is the same product...”<sup>126</sup> In discussing that document, Dr. Robinson verified that Mahar was referring to the mechanically cut mesh as the Colonel’s Original

<sup>122</sup> ETH.MESH.03911107 (Axel Arnaud reporting his interview with Professor Hausler).

<sup>123</sup> *Id.*

<sup>124</sup> ETH.MESH.04985249.

<sup>125</sup> ETH.MESH.00301741 (11/21/05 Email from Lamont, D. re !!!!GREAT NEWS FOR TVT LASER CUT MESH!!!! –Frayed mesh/particle loss); ETH.MESH.00394544 (2/01/06 Global Regulatory Strategy – GYNECARE TVT – Laser Cutting Project); Weisberg Dep. (5/31/13) 487:13-488:7.

<sup>126</sup> ETH.MESH.00687819 (Ex. T-3164).

Recipe:

- Q: He writes, "While we" -- "While we would work with our agency to get this right, my thoughts are that we keep selling regular TVT," meaning the mechanically-cut mesh, right?
- A. Yes.
- Q. "(The Colonel's 'Original Recipe') to those customers that want/love it." Right?
- A. Yes.
- Q. Talking about a piece of plastic that is permanently implanted in a woman's body as the "Original Recipe," right?
- A. That -- yes, that's correct.<sup>127</sup>

Ethicon initially decided that particle loss, elongation curve and flexural rigidity data on laser cut would not be required because they were not "critical to quality." In fact, this news was celebrated as "!!!!GREAT NEWS FOR TVT LASER CUT MESH!!!!" and "less work for all of us."<sup>128</sup> However, because Ethicon wanted to continue to claim the marketing benefit of the Ulmsten/Nilsson series, marketing determined that some testing was needed. This was described as a way to protect the "clinical heritage" of the mesh:

Marketing Need: Keep clinical heritage intact.... In order to continue to claim the use of 7-year data and all clinical studies, the MCM and LCM needed to show similar properties with the physical properties being used as a proxy for the clinical needs.<sup>129</sup>

Ultimately, Ethicon did not end up telling doctors that the mechanically cut mesh and the laser cut mesh are essentially the same, a decision that has kept doctors in the dark about the defects inherent in the mechanically cut TVT mesh, and has led to continued harms and hazards to women. In my opinion as a physician, Ethicon's decision to continue to market and sell the mechanically cut mesh, with all of its defects, and the decision to market the improved laser cut mesh as virtually the same as the old construction (Prolene) mesh, was clearly a

<sup>127</sup> Robinson Dep. (7/25/13) 585:12-23.

<sup>128</sup> *Id.*; ETH.MESH.00584291 (2/15/06 Email from Flatow, J re DVer protocol for particle loss).

<sup>129</sup> ETH.MESH.00858252; *see also* ETH.MESH.00526473; ETH.MESH.02248778 (Kammerer PPT); Hellhammer Dep. (9/11/13) 120-121.

decision by Ethicon to put profits before patient safety. In summary, for the reasons set forth above, it is my opinion to a reasonable degree of medical certainty that the Prolene polypropylene mesh in the TVT has several characteristics that make it improper for use in the vaginal canal including particle loss, fraying, roping, curling, deformation and loss of pore size. These unwanted characteristics can lead to, among other things, an increased inflammatory response (particle loss and fraying) and/or increased pressure on the urethra (roping or curling) or loss of pore size (roping or curling), and can lead to a multitude of injuries, including such as multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon's TVT mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

Moreover, Ethicon did not inform physicians and patients that its mesh was susceptible to these physical deformations that could lead to painful erosions, recurrent, late infections and the need for mesh removal. Nor did Ethicon inform physicians that laser cut mesh had materially different mechanical properties than mechanically cut mesh. By failing to do so, Ethicon did not adequately warn physicians about these important risks, nor by extension, provide surgeons with an opportunity to discuss these risks with their patients.

- B. Ethicon knew that the old construction mesh (Prolene) was not appropriate for use in its TVT device as early as 1998, but failed to modify/change the mesh to a larger pore, lighter weight mesh that would not deform, fray, lose particles, rope, curl, degrade, cause excessive foreign body reactions, and cause excessive shrinkage/contraction because of its economic interest in maintaining its competitive advantage in the MUS**

**market and, therefore, Ethicon put profits before patient safety.**

As stated above, Ethicon knew from the time it launched the TVT with the mechanically cut mesh that it was defective in multiple respects. This is true because the TVT Prolene mesh was known to be made from heavyweight 6 mil fiber and a construction that allowed for mesh curling, roping, fraying, zipping, particle loss, and sharp edges. In fact, beginning in 1998, Ethicon had already established a “mesh improvement project” in order to improve the mesh. Despite the fact that the project yielded an improved mesh, Ethicon never incorporated those improvements into the TVT.

As early as May of 1997, Ethicon knew that the Prolene mesh was not ideal for use in vaginal tissues.<sup>130</sup> In fact, Ethicon knew of a case at that time where a patient had been treated with Prolene mesh, which protruded through the vagina, requiring excision of the mesh. Ethicon knew that the ideal mesh for use in the vagina should not have any fraying or spiky edges, needed to have large enough pores to encourage in-growth, and should have a low mass density to minimize foreign body reaction.<sup>131</sup> Ethicon then embarked on a project to improve the Prolene mesh used in the TVT product and Ethicon’s hernia products. Among the characteristics they sought to improve were the product curling, zipping and unraveling of the mesh after cutting, and crumbling of the mesh.<sup>132</sup> Ethicon noted that if the Prolene mesh was pulled in one direction, the mesh would curl up into a tube, and the mesh would remain in a rolled condition even after the force of the pulling was no longer on the mesh.

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<sup>130</sup> ETH.MESH.12006257

<sup>131</sup> ETH.MESH.12006257

<sup>132</sup> ETH.MESH.09264945

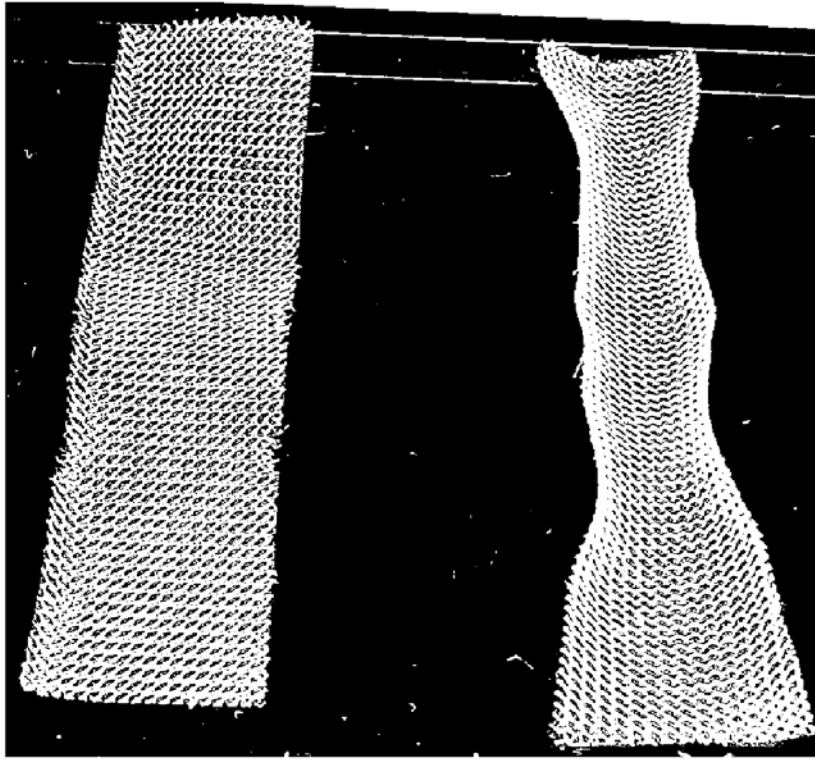


Figure 1 – Control mesh sample before and after the application of the force. A clear picture of mesh curling results.

Ethicon also referred to the original construction 6 mil Prolene mesh as a mesh that was known for its “bad” curling quality.<sup>133</sup> Ethicon ultimately changed the flat Prolene mesh used for hernia repair to address these issues, making changes to the construction of the mesh to address the bad curling quality of the mesh, and at the same time, changing to a lighter weight, 5 mil mesh construction.<sup>134</sup> The change in the mesh construction also made the mesh less likely to fray and lose particles.<sup>135</sup> Despite Ethicon’s original intent to incorporate the new construction material which was lighter weight and had improved resistance to curling, fraying, and particle loss,<sup>136</sup> Ethicon continued and still continues to use the original, old, old

<sup>133</sup> ETH.MESH.02182844, ETH.MESH.00946834.

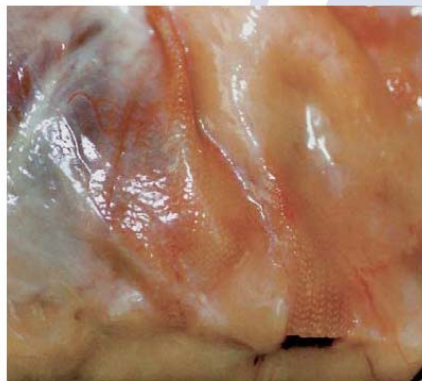
<sup>134</sup> ETH.MESH.00782152.

<sup>135</sup> ETH.MESH.020008684.

<sup>136</sup> ETH.MESH.09264884.

heavyweight 6 mil construction mesh for the TVT products.<sup>137</sup>

The flaw in the construction of the TVT heavyweight Prolene mesh which allows it to curl into a tube after tensioning or pulling on the mesh and not return to its original shape, combined with the heavyweight and small pore nature of the mesh, causes the mesh to fold up and become hard post-implantation. Ethicon continued to be aware of this continuing defect in the mesh well after the Prolene mesh improvement project was completed and the company changed the construction of its Prolene hernia mesh.<sup>138</sup> Ethicon was also aware that lightweight materials were less likely to fold up post implantation and integrated better with surrounding tissues,<sup>139</sup> but continued to use the heavier 6 mil fibers. The lightweight materials were also much better at resisting crumpling and less likely to have sharp edges during tissue integration.<sup>140</sup>



Traditional polypropylene mesh. 90 days post-implantation. Fold development (in-vivo study)



Lightweight VYPRO\* II mesh. 90 days post-implantation. Fold-free incorporation (in-vivo study)

Ethicon continued to have problems with mesh quality in the TVT mesh after the Prolene mesh improvement project was complete, but never incorporated those changes into

<sup>137</sup> ETH.MESH.09275875, ETH.MESH.02030355.

<sup>138</sup> ETH.MESH.05918776.

<sup>139</sup> ETH.MESH.05446129.

<sup>140</sup> Ethicon Tissue Reinforcement Solutions, 8/21/2004.

the TVT mesh. After the improved construction 5 mil Prolene mesh replaced the 6 mil mesh Prolene mesh for flat hernia repair, Ethicon noted continuing problems with the Prolene mesh in the TVT, noting inconsistent tape width,<sup>141</sup> and fraying and particle loss from the TVT mesh.<sup>142</sup> Doctors reported to Ethicon that the quality of the mesh was terrible, and that particles were falling off the mesh, which was worse when the mesh was elongated.<sup>143</sup>

Even before the TVT was launched in the United States, Ethicon was looking at ways to change the existing mesh tape construction in order to improve the appearance of the mesh and to alleviate problems experienced during the manufacturing process.<sup>144</sup> Ethicon also knew prior to launching the TVT for sale in the United States that if the tape became twisted, it would reduce the effectiveness of the TVT procedure, and evaluated laser-cut samples of the TVT mesh as opposed to the mechanically cut mesh.<sup>145</sup> The project which looked at laser cutting the mesh was part of the “TVT improvement project” which began prior to the launch of the TVT in the United States. Included in the goals of the TVT improvement project were a mesh that was safer, eliminated abrasion, rough edges, and narrowing of the mesh under tension.<sup>146</sup> Ethicon evaluated feedback from surgeons who compared the Laser cut mesh to the guillotine (mechanically) cut mesh, and were told that the laser cut mesh had a more regular appearance, the mesh did not stretch as much as the current guillotine cut mesh, and there was a marked reduction in the amount of loose ends falling off.<sup>147</sup> Testing also showed that the mechanically cut mesh stretched 90% more than the laser cut mesh when force was applied to the mesh. However, despite having a laser cut mesh available which had less rough edges, less

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<sup>141</sup> ETH.MESH.12002601.

<sup>142</sup> ETH.MESH.00863405.

<sup>143</sup> ETH.MESH.02180833.

<sup>144</sup> ETH.MESH.10591870.

<sup>145</sup> ETH.MESH.12009079.

<sup>146</sup> ETH.MESH.12009262; ETH.MESH.12009276.

particle loss, and less narrowing and deformation under tension, Ethicon chose to launch the TVT in the United States with the guillotine (mechanically) cut mesh.

Ethicon did not change the Prolene mesh in its TVT device despite having better and safer options available for economic reasons. Ethicon believed that continued use of the TVT mesh gave the company an economic and competitive advantage in marketing the product because they could continue to use the existing clinical data on the product to market the device, while if the mesh was changed, the existing clinical data would be obsolete.<sup>148</sup> Dr. Brigitte Hellhammer testified that despite having incorporated the use of the lightweight, large pore Ultrapro mesh in vaginal tissues for the treatment of pelvic organ prolapse, the Ultrapro was never used by Ethicon in a device used for the treatment of stress urinary incontinence largely because the company wanted to continue to rely on the Ulmsten/Nilsson series of studies on 130 patients performed with the TVT device.<sup>149</sup> Dr. Arnaud also confirmed that the company did not want to change anything with the mesh because of the exiting clinical data on the product.<sup>150</sup> It is my opinion to a reasonable degree of medical certainty that Ethicon was negligent in failing to correct the defects in the TVT mesh as the company had knowledge of the defects and failed to correct the defects with products and solutions that were already available to the company because it put its economic interests above the safety of patients.

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<sup>147</sup> ETH.MESH.10182456.

<sup>148</sup> ETH.MESH.03911107.

**C. Ethicon's TVT's design is flawed because it cannot adequately describe, inform or explain to physicians how to properly "tension" the TVT and the mesh shrinks, contracts, ropes and curls making it impossible to tension.**

TVT stands for and has consistently been marketed by Ethicon as "Tension-free Vaginal Tape." Presumably, this means the mesh should be inserted under the urethra without tension. However, the term "tension-free" is misleading. In practice, too little or no tension results in failure to treat the underlying condition of urinary incontinence. On the other hand, as suggested by Ethicon's own internal documents, too much tension can result in serious complications such as retention and urethral erosion.<sup>151</sup> Also, as discussed above, because the mesh shrinks, contracts, ropes and curls, it is impossible or extremely difficult to properly tension the mesh.

The IFU provides little guidance on proper tensioning of the TVT. Specifically, once the tape is placed, surgeons are simply instructed to pull the needles upwards "to bring the tape (sling) loosely, i.e. without tension, under the midurethra" and to "adjust the tape so that leakage is limited to no more than one or two drops."<sup>152</sup> The IFU's Warnings and Precautions section cautions surgeons to "[e]nsure that the tape is placed with minimal tension under the mid-urethra."<sup>153</sup> Yet in the very same section, the surgeon is instructed "to place the tape tension-free in the mid-urethral position" to minimize the risk of de novo detrusor instability.<sup>154</sup> Finally, the IFU's "Adverse Reactions" section provides that "over correcting, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction."<sup>155</sup> The IFU's conflicting instructions with regard to tensioning of the tape,

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<sup>149</sup> Deposition of Brigitte Hellhammer, MD, September 11, 2013.

<sup>150</sup> Deposition of Axel Arnaud, July 19, 2013 36:15-37:3.

<sup>151</sup> ETH.MESH.05529274; ETH.MESH.04044797; ETH.MESH.05529653; ETH.MESH.00161131.

<sup>152</sup> Eth.Mesh.05222686, emphasis added.

<sup>153</sup> Eth.Mesh.05222687, emphasis added.

<sup>154</sup> Eth.Mesh.05222567, emphasis added.

<sup>155</sup> Eth.Mesh.05222687, emphasis added.

i.e. “without tension,” “with minimal tension,” “tension-free” and “overcorrecting, i.e. too much tension” are clearly confusing and inadequate despite the fact that Ethicon knew as early as 2000 that improper tensioning could lead to complications and, therefore, the IFU needed to be “clear.”<sup>156</sup> These tension issues are compounded when the mesh contracts, shrinks and deforms as discussed above.

Ethicon recognized as far back as November 1999 that TVT tension adjustment was considered “high need” and surgeons had a hard time sticking to proposed technique.<sup>157</sup> By 2000, Ethicon recognized that excess tensioning during initial placement could create a risk of erosion.<sup>158</sup> In an email dated February 13, 2001, Medical Director Axel Arnaud wrote “there is clearly a need for standardization of the TVT procedure to avoid excessive tension on the mesh. We should aggressively work in order to develop a product and I would like to take the responsibility for this.”<sup>159</sup> In May 2002, Axel Arnaud continued to recognize the need to develop a safer device “in order to prevent excess tension of the tape.”<sup>160</sup> In 2003, Ethicon recognized that a challenge with the TVT procedure remained complications “associated with over-tensioning of the sling and the inability to obtain precise biofeedback and adjustment during and/or after the procedure.”<sup>161</sup> Indeed, Dr. Nilsson, the “father of the TVT”, discussed that the TVT done under general anesthesia with a cough test was 70% successful compared to a 85% success rate when done with local anesthesia and a cough test.<sup>162</sup>

The lack of clear direction on tensioning in the IFU is demonstrated in September 2004 emails from Sales Representative Shannon Campbell in which she writes: “What is a huge

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<sup>156</sup> Eth.Mesh.01317523.

<sup>157</sup> Eth.Mesh.05641096.

<sup>158</sup> Eth.Mesh.05529274; Eth.Mesh.04044797; Eth.Mesh.05529653; Eth.Mesh.00161131.

<sup>159</sup> Eth.Mesh.03915380.

<sup>160</sup> Eth.Mesh.03907468.

<sup>161</sup> Eth.Mesh.00259271.

<sup>162</sup> Eth.Mesh.04048515 at Eth.Mesh.0408516 7/01/08 KOL Interview: Carl G. Nilsson, Project Scion.

challenge to a rep trying to make this right, is that we really don't know what the right amount [of tensioning] is. We know this is a quick fix to the problem, but not a clinically backed solution. It's almost like trying to decide if a 8, 10, or 12 mm Hagar dialator is best for tensioning TVT with the patient under general. We learned the cough test, but relied on surgeons experience with the tensioning under general.... This has been such a gray area and everyone seems to have their own tensioning technique.” She continues: “I feel I got a little grilled over my suggestion of tensioning, yet there is no clear direction on tensioning. I’m not a rebel looking for my own way of doing this. I’m a rep trying to figure out what is best from my experience with surgeons and what I see the product doing in the OR. ...The reason for my question is to see if someone had the proper wording we need to use as rep’s that eliminates our liability with the product in the OR concerning tensioning.”<sup>163</sup>

In December 2006, Ethicon Marketing Director Allison London-Brown referred to tensioning as a “sticky” question and acknowledged that “we cannot accurately describe [tensioning] in writing.”<sup>164</sup> Meanwhile, Ethicon knew that patients were suffering from erosions and, in fact, would often blame the physician as the cause of the erosion for putting “too much tension on the device.”<sup>165</sup> At least by 2007, it seems Ethicon finally acknowledged that “TVT has never been tension free!” despite years of marketing it otherwise.<sup>166</sup> For example, in 1999, Ethicon utilized marketing pieces for “TVT Tension Free Vaginal Tape” which claimed “Tension-free Support Only When Needed” which “reduces possibility of urethral erosion.”<sup>167</sup> A 2001 marketing piece for “Gynecare TVT Tension-Free Support for Incontinence” claimed “most complications are minor and are avoidable with adherence to

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<sup>163</sup> Eth.Mesh.00864503.

<sup>164</sup> Eth.Mesh. 01784428-01784435.

<sup>165</sup> Eth.Mesh.02625055, Eth.Mesh.02627811, Eth.Mesh.02625375, Eth.Mesh.02625155.

<sup>166</sup> Eth.Mesh.06861473.

procedural technique and instructions for use.”<sup>168</sup> In 2004, during the same time period when Shannon Campbell was lamenting the problems with tensioning, Ethicon continued to promote TVT as “the leader in midurethral sling devices” for “tension-free support for incontinence.”<sup>169</sup> Even after Ethicon acknowledged that TVT has never been tension free, the company continued to market it as “Tension-free Support for Incontinence.”<sup>170</sup>

Physicians were also not informed in Ethicon’s product IFU that tension on the mesh arms decreases effective pore size and interferes with incorporation into tissue. Engineer Christophe Vailhe testified that “excessive uniaxial tension on the mesh will decrease the pore size and lead to poor tissue integration.”<sup>171</sup> In addition, Mr. Vialhe testified that “excessive tension on the mesh would lead to the decrease in pore size that can lead to poor tissue integration . . . .”<sup>172</sup> Engineer Dan Burkley also testified that once the TVT Prolene mesh is either stretched by the surgeon or stretched by in-vivo due to forces in a women’s body, it can alter the structure of the pores.<sup>173</sup>

The IFU failed to adequately instruct surgeons on the critical subject of tensioning as repeatedly acknowledged by Ethicon. Ethicon now claims that “tension-free” does not really mean tension-free, but rather, means less tension than as seen in the Burch procedure.<sup>174</sup> Yet, despite its awareness of the problems associated with tensioning, Ethicon failed to revise the conflicting and ambiguous IFU to provide adequate direction on the proper amount of tensioning even though Ethicon was fully aware that improper tensioning could lead to serious complications such as urinary retention, voiding difficulties, de-novo detrusor instability,

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<sup>167</sup> Eth.Mesh.00161444.

<sup>168</sup> Eth.Mesh.00339437.

<sup>169</sup> Eth.Mesh.00160813.

<sup>170</sup> Eth.Mesh.00164643; Eth.Mesh.00339053.

<sup>171</sup> Vailhe, 6/20/13, 224:10-226:21.

<sup>172</sup> Vailhe, 6/20/13, 224-226.

<sup>173</sup> Burkley 5/22/13 430:3-431:10.

dyspareunia, vaginal extrusion and urethral erosion. In addition, the design of the device and the mesh is problematic because it shrinks, contracts and deforms exacerbating the issues discussed above.

Ethicon failed to act as a reasonable and prudent medical device manufacturer by failing to design the TVT in a way that it could be properly tensioned and by failing to inform physicians how to properly tension TVT and that improper tension could affect the pore size of the mesh. These failures by Ethicon have resulted in numerous injuries to patients, including, but not limited to chronic pain, urinary retention, voiding difficulties, de-novo detrusor instability, dyspareunia, and vaginal extrusion and urethral erosion.

As one sales representative noted in an email to Dan Smith, the inability of Ethicon to properly communicate how to tension the TVT had safety and legal ramifications:

I feel I got grilled on my suggestion of tensioning, yet there is no clear direction on tensioning.... My goal is not to get the tape changed, yet strive to place the mesh as designed without altering it. The surgeon does own the responsibility of proper delivery and placement. The fact is, they look to us as reps to show them the proper placement techniques.

The reason for my question is to see if someone had the proper wording we need to use as reps that eliminates our liability with this product in the OR concerning tensioning.<sup>175</sup>

In my opinion, Ethicon failed to properly test the unique tensioning issues related to the TVT prior to marketing the device. Ethicon left physicians without sufficient information about how to properly remove sheaths and/or properly tension the TVT mesh in light of the lack of uniformity with tensioning and for failing to account for problems with the mesh like contraction, shrinkage and deformation when tensioning. Ethicon improperly managed the sheath/tension problem by telling individual physicians “tips and tricks” including the Surgeon’s Resource Monograph. This advice necessarily could not reach hundreds of surgeons

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<sup>174</sup>Smith 6/4/13 524:20-525:13.

who did not get the “tips and tricks” from sales representatives or Ethicon employees. Such information should have been put in the IFU. Because physicians did not have the proper information, they could not impart the information to their patients or properly consent their patients for all of the risks associated with over-tensioning mesh such as roping, curling, fraying and all of the associated injuries.

**D. Ethicon’s Prolene mesh in the TVT is not suitable for permanent implant because the Material Safety Data Sheets (“MSDS”) for polypropylene resin used to manufacture polypropylene states that polypropylene is incompatible with strong oxidizers such as peroxides which are readily found in the vagina**

According to Ethicon Medical Director, Dr. Martin Weisberg, a Material Safety Data Sheet (MSDS) is “a document that discusses the product, the composition, any potential hazards from it . . . Generally, the safety particular of products.”<sup>176</sup> As it relates to polypropylene, I have reviewed several MSDSs for polypropylene resin used to manufacturer meshes used in various pelvic floor meshes. All of the MSDSs discussed below are available to the public.

Sunoco, the manufacturer for the polypropylene resin used to manufacture Ethicon’s pelvic floor products lists the possibility that polypropylene mesh is incompatible with strong oxidizers. This is documented by the Sunoco MSDS<sup>177</sup> from April 13, 2005 which states in relevant part:

**10. STABILITY AND REACTIVITY**

**• INCOMPATIBILITY**

The following materials are incompatible with this product: Strong oxidizers such as chlorine, peroxides, chromates, nitric acid, perchlorates, concentrated oxygen, sodium hypochlorite, calcium hypochlorite and permanganates. Chlorine; Nitric acid;

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<sup>175</sup> ETH.MESH.00864503.

<sup>176</sup> Weisberg Dep. (8/9/13) 909:2-9.

<sup>177</sup> ETH.MESH.02026591 at 6591-6595.

This warning is important because it states what the polypropylene in the TVT is incompatible with strong oxidizers like peroxides, which is particularly important because the vagina is a natural and ready source of peroxides. In fact, the vagina is a ready source of hydrogen peroxide production. In a paper titled, "The in vitro effects of hydrogen peroxide on vaginal microbial communities,"<sup>178</sup> the amount of hydrogen peroxide produced by the lactobacillus species is reported. The paper states, "Hydrogen Peroxide reached concentrations of from 0.05 to 1.0 mM, which under intensive aeration increases even up to 1.8 mM." This work confirmed the earlier research in the paper titled, "Hydrogen peroxide produced by Lactobacillus species as a regulatory molecule for vaginal micro-flora."<sup>179</sup> "The human body also contains other agents, such as hydrocarbons and various bacteria that impacts the MSDS discussed above and the warnings contained therein."<sup>180</sup>

The Prolene MSDS indicates that if you put the polypropylene used to make the TVT mesh in an environment with peroxides, it will start to break down. Given the information available to Ethicon concerning the dangers of polypropylene coupled with the warnings and other contents of the MSDSs and related documents, at a minimum, Ethicon should have conducted clinically relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene used in the TVT to alter inside a woman's pelvis (as well as

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<sup>178</sup> M Strus in FEMS Immunol Med Microbiol, 2006 October; 48(1:56-63).

<sup>179</sup> Med Dosw Microbiol. 2004:56(1):67-77.

<sup>180</sup> HB Moon, "Occurrence and accumulation patterns of polycyclic aromatic hydrocarbons and synthetic musk compounds in adipose tissues of Korean females" 2011; "Determination of volatile purgeable halogenated hydrocarbon in human adipose tissue and blood stream," from Bulletin of Environmental Contamination and Toxicology Volume 23 Issue 1 pp 244 – 249 published in 1979; Environmental Health Perspective's, Vol. 60 pp. 127-131, Henry Anderson, "Utilization of Adipose Tissue Biopsy and Characterizing Human Halogenated Hydrocarbon Exposure", N. Das, Journal Biotechnology Research International 2010, Vol 2011, Article ID 941810 titled, "Review Article: Microbial Degradation of Petroleum Hydrocarbons Contaminant: An Overview", "Health, Safety and Environment Fact Sheet: Hazardous Substances from CAW/TCA." (www.caw.ca) August 2011, D. Lithner, 2011, entitled "Environmental and Health Hazards of Chemicals in Plastic Polymers and Products", University of Gothenburg.

other complications). If so, what materials are released into the body as a result, and what impact would those materials have on the body. The fact that the mesh in the TVT is susceptible to breaking down when in contact with peroxides makes it an unsuitable material to be placed in the vagina for the reasons discussed above. At the very least, Ethicon should have disclosed this information to physicians and patients considering use of their pelvic mesh.

Despite the warning in the MSDS for the polypropylene resin used to manufacture the TVT mesh cautioning against contact with strong oxidizers such as peroxides, there is no evidence that Ethicon tested the mesh to see if the peroxides in the vagina broke it down or informed surgeons about this important information contained in this or various other Manufacturer Safety Data Sheets (MSDS) regarding the use of polypropylene.

The fact that the MSDS for the TVT mesh warned against contact with strong oxidizers such as peroxides is information that a doctor would want to consider before implanting a permanent device in a woman's body for the rest of her life as substances in the vagina could cause the breakdown of the product, yet there Ethicon never informed doctors about the warning in the MSDS. As a result, Ethicon failed to act like a reasonable and prudent medical device manufacturer.

**E. Ethicon's Prolene mesh is not suitable for permanent implant because the toxicity testing of the polypropylene mesh revealed that it was cytotoxic;**

Cytotoxicity means toxicity to the cells causing cell injury or death.<sup>181</sup> In a May 26, 2000, Ethicon Memo titled "Review of biocompatibility on the tension-free vaginal tape (TVT) system for compliance to FDA,"<sup>182</sup> the review contains a "Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device" from August 8, 1997.<sup>183</sup> The Cytotoxicity Assessment states

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<sup>181</sup> Robinson Dep. (9/11/13) 1091:11-21.

<sup>182</sup> ETH.MESH.06852118 at 2118-2129 (5/26/2000 Biocompatibility Review).

<sup>183</sup> ETH.MESH.06852120 (8/8/1997 Cytotoxicity Risk Assessment).

“there is some evidence to suggest that the PP [polypropylene] mesh from the sterile Ulmsten device may have cytotoxic potential.”<sup>184</sup> In addition, ISO Elution testing “resulted in marked cytotoxicity in tests conducted at Ethicon (Scotland).”

According to former Ethicon Medical Director, Dr. David Robinson, Ethicon never performed “a single long-term study . . . to determine whether or not the Ethicon mesh is clinically cytotoxic in women.”<sup>185</sup> In addition, in its IFUs and Patient Brochures, Ethicon never informed physicians or their patients about the possibility of cytotoxicity.<sup>186</sup> Dr. Robinson testified that if there is a clinical related outcome related to cytotoxicity, it is reasonable for physicians to want to know that the mesh in the TVT product had been tested multiple times to be severely or marked cytotoxic.<sup>187</sup>

Cytotoxicity can cause death to cells that can lead to an inflammatory response leading to a multitude of injuries, including serious adverse complications such as erosions, chronic pelvic pain, recurrence, worsening incontinence, dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction or the need for additional surgeries. Ethicon did not undertake any long term testing to determine whether the marked cytotoxicity found in the TVT mesh had long term consequences for permanent human use. This is true despite the fact that its own test results showed the mesh to be cytotoxic.

Because of the dangers and consequences that occur as a result of cytotoxicity, the fact that Ethicon had positive tests for cytotoxicity and did nothing to test for it makes the mesh in the TVT not suitable for permanent implantation. In addition, the potential for cytotoxicity or cell death is important information that physicians need to know in order to pass the

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<sup>184</sup> *Id.* and Robinson Dep. (9/11/13) 1098:23-1099:9.

<sup>185</sup> Robinson Dep. (9/11/13) 1101:24-1102:5.

<sup>186</sup> Robinson Dep. (9/11/13) 1114:15-18.

<sup>187</sup> Robinson Dep. (9/11/13) 1115:5-19.

information on to their patients so that an informed decision can be made about whether to have a permanent medical device implanted in their body. It is clear from Ethicon's Medical Director David Robinson that this information was never passed on to physicians despite the fact that it would have been reasonable for physicians to have this information. As a result, Ethicon did not act as a reasonably prudent medical device manufacturer in it failed to inform physicians and their patients about the risk of its mesh being cytotoxicity.

**F. Ethicon's warnings and disclosures of adverse events in its TVT Instructions for Use ("IFU") are inadequate based on the adverse reactions and risks associated with the TVT that have been known to Ethicon from the time the TVT was first sold and marketed**

The purpose of the IFU is for a medical device manufacturer to provide physicians with the information necessary for them to make decisions regarding the used a medical device for a particular patient. In addition, the IFU should disclose adverse reactions and risks known to the medical device manufacturer to the physician so that the risks can be relayed to the patient and an informed decision regarding the use of the product can be reached. Throughout my education, training, surgical and clinical practice, I have reviewed numerous IFUs for a variety of products, including mesh products in order to understand the proper way to use the device and to gain knowledge about the complications and adverse events associated with a device. I have extensive clinical experience with IFUs and instructing patients about the adverse events/risks contained in the IFU. Similar to Medical Directors, Dr. Martin Weisberg and Dr. David Robinson, I have gained expertise in IFUs through my extensive clinical experience reviewing IFUs, and consenting patients regarding IFUs, including Ethicon's own pelvic mesh products including the TVT line and Prolift.

Catherine Beath, Ethicon's former Vice President of Quality Assurance and Regulatory

Affairs, testified that “physicians should be made aware of all the significant safety risks associated with the product in the IFU.”<sup>188</sup> And, “a reasonably prudent medical device company would continually update the label consistent with developing data and information that becomes known to the company” when it is appropriate.<sup>189</sup> Similarly, former Medical Director Dr. David Robinson testified that the warnings and adverse event section of the IFU should include all significant risks and complications related to the procedure and the mesh.<sup>190</sup> According to Dr. Robinson, a device manufacturer must include this information because you want to make sure the doctors have all the information they need to adequately inform patients who are deciding to use the product.<sup>191</sup> According to Ethicon Medical Director Dr. Martin Weisberg, the goal of the IFU is to communicate the most important safety risks attributable to the TVT device and that an IFU should never exclude known hazards or complications.<sup>192</sup>

Dr. Weisberg also believes that an IFU should not knowingly underestimate the risks of using the product.<sup>193</sup> And, if an IFU excludes known complications or understates the risks, it “fails in one of its principal purposes.”<sup>194</sup> Finally, Peter Cecchini, a 43 year Ethicon employee and Regulatory Fellow and the person responsible for the TVT 510K, testified that the “regulatory standard for the IFU is the known risks are supposed to be included in the adverse reactions.”<sup>195</sup> Mr. Cecchini testified that he relies on medical affairs to make sure he knows the known risks so they can be included in the IFU.<sup>196</sup>

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<sup>188</sup> Beath Dep. (7/12/13) 592:7-11.

<sup>189</sup> Beath Dep. (7/11/13) 198: 8-13.

<sup>190</sup> Robinson Dep. (9/11/13) 238:12-25.

<sup>191</sup> Robinson Dep. (9/11/13) 239:1-11.

<sup>192</sup> Weisberg Dep. (8/9/13) 659:19-660:15.

<sup>193</sup> *Id.* at 960:13-16.

<sup>194</sup> *Id.* at 961:10-17.

<sup>195</sup> Cecchini, 10/22/12, 65:5-12.

<sup>196</sup> Cecchini, 10/22/12, 65:18-24.

**1. The TVT IFU Did Not Include All Known Risks, Was Inaccurate and Was Not Updated.**

**a. The IFU did not include all known risks.**

As noted above, Ethicon did not include the proper information concerning the dissection in the original IFU. There were also numerous other potential risks that were not included in the IFU at launch.

If you compare the adverse reactions/risks in the TVT IFUs to the adverse reactions/risks that were available and known to Ethicon at the time of the launch of TVT, it is clear that there are numerous adverse events absent from the IFU. From the time TVT was launched in the United States in December of 1998 to the present day, there have been ten versions of the Ethicon TVT IFU. These include the following versions: October, 1998, April, 1999, May 1999, September 8, 2000, December 22, 2003, February 11, 2005, April 7, 2006, October 13, 2008, November 29, 2010, and May, 2015. A chart showing the Adverse Reactions/Risks section for each version of the TVT Instructions for Use is set forth below.

<b>Product</b>	<b>Production Prefix</b>	<b>Start Bates</b>	<b>End Bates</b>	<b>First Use Date</b>	<b>Last Use Date</b>	<b>Adverse Reactions / Risks</b>
<i>TVT</i>	ETH.MES H	0020347 7	002034 82	10/27/98 (U.S Launch IFU)	04/11/99	<p>*Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation</p> <p>*As with all foreign bodies, PROLENE mesh may potentiate and existing infection. The Plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination</p> <p>*Over correction i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction</p>
<i>TVT</i>	ETH.MES H	0020451 4	002045 19	04/11/99	05/18/99	Same as 10/27/1998 IFU

TVT	ETH.MES H	0020456 2	002045 93	05/18/99	09/08/00	<p>* Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.</p> <p>* Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.</p> <p>* As with all foreign bodies, PROLENE Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE Mesh is designed to minimize the risk of contamination.</p> <p>* Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.</p>
TVT	ETH.MES H.	5225354	522538 5	09/08/00	11/26/03	Same as 05/18/1999 IFU
TVT	ETH.MES H.	2340306	234036 9	12/22/03	02/11/05	Same as 05/18/1999 IFU

TVT	ETH.MES H.	2340471	234050 3	02/11/05	04/07/06	Same as 05/18/1999 IFU
TVT	ETH.MES H.	5222673	522270 4	4/07/06	10/07/08	Same as 05/18/1999 IFU
TVT	ETH.MES H.	2340504	234056 7	10/13/08	11/22/10	Same as 05/18/1999 IFU
TVT	ETH.MES H.	3427878	342794 5	11/29/10	May, 2015	Same as 05/18/1999 IFU.
TVT	N/A	N/A	N/A	May, 2015	To Present Day	<p>*Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra, or bowel, may occur and may require surgical repair.</p> <p>*Transitory local irritation at the wound site may occur.</p> <p>*As with any implant, a foreign body response may occur. This response could result in</p>

					<p>extrusion, erosion, exposure, fistula formation and/or inflammation.</p> <p>*Mesh extrusion, exposure, or erosion into the vagina or other structures or organs.</p> <p>*As with all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE mesh may potentiate an existing infection.</p> <p>*Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.</p> <p>*Acute and/or chronic pain.</p> <p>*Voiding dysfunction.</p> <p>*Pain with intercourse which in some patients may not resolve.</p> <p>*Neuromuscular problems, including acute and/or chronic pain the groin, thigh, leg, pelvic and/or abdominal area may occur.</p> <p>*Recurrence of incontinence.</p> <p>*Bleeding including hemorrhage, or hematoma.</p> <p>*One or more revision surgeries may be necessary to treat these adverse reactions.</p> <p>*PROLENE mesh is a permanent implant that integrates into tissue, In cases in which the PROLENE mesh needs to be removed in part or whole, significant dissection may be required.</p> <p>*Seroma</p> <p>*Urge incontinence</p> <p>*Urinary frequency</p>
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						*Urinary Retention *Adhesion formation *Atypical vaginal discharge *Exposed mesh may cause pain or discomfort to the patient's partner during intercourse. *Death
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In all six versions of the TVT IFU from May 19, 1999 to May of 2015, the Adverse Reactions/Risks section has remained exactly the same. It reads as follows:

#### ADVERSE REACTIONS

- \* Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- \* Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- \* As with all foreign bodies, PROLENE Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE Mesh is designed to minimize the risk of contamination.
- \* Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.<sup>197</sup>

Despite only listing the above adverse reactions/risks, it is clear from the testimony of Senior Ethicon Employees in both the Medical Affairs and Regulatory Affairs that every adverse reaction/risk that Ethicon has scientific knowledge of today, it had scientific knowledge about at the time the TVT was first sold in and certainly in 2004 when the first TVT was sold, marketed and launched. Medical Director, Piet Hinoul testified that Ethicon understood the following adverse events occurred from the time the TVT was first sold, years before the first TVT was sold:

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<sup>197</sup> ETH.MESH.02340406.

Erosions through vaginal epithelium Infection  
 Pain  
 Urinary Problems  
 Erosions that could decrease patient's quality of life  
 Dyspareunia  
 Need for additional surgeries  
 Need for the removal of device  
 Urinary Tract Infections  
 Dysuria  
 DeNovo Urgency  
 Mesh Exposure  
 Fistula Formation  
 Hematoma  
 Abscess Formation  
 Narrowing of vaginal wall  
 Erosion which can occur any time in future  
 Contracture of mesh causing pain  
 Complications making it impossible to have sexual relations  
 Worsening Incontinence

Yet, none of these were in the TVT IFU at launch. There have been two significant updates to the Adverse events section of the TVT IFU since launch, one in May of 1999, and one in May of 2015. The May, 1999 updates to the IFU, including the addition to the Adverse Reactions section, were part of a corrective action plan taken by Ethicon due to a number of Serious Adverse Events being reported with the TVT device, 25 of which came to light in the two months prior to the IFU update. The majority of these Adverse events involved injury to vessels, bladder or bowel.<sup>198</sup> The Adverse Events section of the IFU was updated in May of 1999 to include the following:

- Punctures of lacerations of vessels, nerves, bladder, or bowel may occur during needle passage and may require surgical repair.**

In addition to the updates to the Adverse Reactions section of the IFU, the Warnings and precautions section was updated to include the following statements:

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<sup>198</sup> ETH.MESH.07424335.

- The TVT procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimize risks.
- Retropubic bleeding may occur postoperatively. Observe for symptoms or signs before releasing patient from hospital.

The May, 2015 IFU included a large number of significant updates, including warnings about pain, chronic pain, dyspareunia for the patient and/or her partner, need for multiple surgeries, and the difficulty in removing all or part of the device. These adverse events, which were added to the TVT IFU in May of 1999 and May of 2015, are all risks that Ethicon knew of at the time of launch of the TVT, and should have been included in the IFU since launch.

In addition, as discussed more fully throughout this report, Ethicon failed to include significant risks in its IFU related to the Prolene polypropylene mesh, including potential cytotoxicity, association with tumor formations and that the mesh can degrade, shrink and contract. The IFU also fails to include risks associated with the Prolene mesh, including chronic foreign body reaction, fibrotic bridging, infections/biofilms, fraying/particle loss and roping/curling of the mesh. Moreover, the IFU fails to inform physicians that patients may require multiple surgeries to treat erosions, that erosions could be severe and untreatable, that patients could endure lifelong severe pain or dyspareunia/painful sex, removing the mesh and revision surgeries can be complicated and challenging for both the patient and physician, and complete removal of the TVT mesh is likely impossible.

Medical Director Dr. Weisberg testified that Ethicon did not include: “permanent, lifelong, worsening and debilitating pain”, lifelong risk of surgical repairs for erosions, “severe or chronic inflammation“, collapse under strain and cause fibrotic bridging, that the product can degrade, that polypropylene is cytotoxic, severe erosion, or particle loss.”<sup>199</sup>

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<sup>199</sup> Weisberg Dep. (8/9/13) 968:12-972:21.

But Ethicon did not disclose this information to physicians in its IFUs regarding characteristics of the old construction mesh in TVT, including that it is small pore, heavy weight mesh, it degrades over time, causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, roping and curling of the mesh, and that it deforms and the pores collapse with tension. In fact, Ethicon medical director Piet Hinoul testified if Ethicon did warn that roping, curling and particle loss can cause pain and erosions Ethicon would have to take the mesh off the market.<sup>200</sup>

Moreover, the IFU failed to inform physicians of the frequency, duration and severity of the risks associated with the TVT device until the May, 2015 IFU update. In addition, former Medical Director, Dr. David Robinson, testified that Ethicon never informed physicians that patients may require multiple surgeries to treat erosions, that erosions could be severe and untreatable, and that patients could endure lifelong severe pain or dyspareunia/painful sex. This is true despite, as discussed above, Ethicon had scientific knowledge of the risks at the time of launch.

**b. The IFU inaccurately portrayed risks.**

In addition to excluding certain known risks, Ethicon significantly downplayed the risks that it actually listed in its IFU. This is especially true with respect to erosions. On the topic of erosions, in the Adverse Event/Risks section in the TVT IFU, in place from the time of launch until present day, it states:

Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.

This language significantly downplays the permanent nature of erosions and suggests to

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<sup>200</sup> Trial testimony of Piet Hinoul, *Batiste v. Ethicon*, page 67.

physicians that erosions are a “transitory” or temporary problem. As shown in an email exchange between Ethicon’s Associate Medical Director of Worldwide Customer Quality Meng Chen, M.D., Ph.D and Bryan Lisa in the Regulatory Affairs Department, it was clear that the adverse events were not “transitory.” Chen wrote, “Pardon me again, from what I see each day, these patient experiences are not “transitory” at all.”<sup>201</sup>

Ethicon also had scientific evidence that erosions could occur many years after implantation of the device. In Minutes from June 22, 2001 Scientific Advisory Committee on Pelvic Floor Repair, it was a “Consensus: Erosion is a risk. Erosion, possibly an infection response. Typically seen by 3 mos, usually by 6-12 mos. Can present late, 3 years. To vagina- not a good situation. To bladder, urethra or rectum-a very bad situation.”<sup>202</sup> “There have been reports of erosions into the urethra that are not picked up until months even years after the procedure.”<sup>203</sup> In October 2002, Medical Director Dr. Martin Weisberg was involved in email exchange with European Science Director Axel Arnaud about downplaying risks with respect to erosions. Specifically, Dr. Arnaud suggested to Dr. Weisberg that Ethicon needed “to be more elusive” when discussing potential complications like erosions.<sup>204</sup>

According to Medical Director Dr. Martin Weisberg and former Medical Director Dr. David Robinson, Ethicon never disclosed or warned doctors or patients in IFUs or Patient Brochures that the use of TVT slings can cause lifelong risk of erosions.<sup>205</sup> Despite the fact Ethicon had scientific feedback from one of its own doctors that experiences were not transitory and that she had concerns about the IFU and the transitory language, Ethicon never informed physicians or disclosed it in its IFU.

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<sup>201</sup> ETH.MESH.04093125 (1/29/09 Email between Meng Chen and Bryan Lisa).

<sup>202</sup> ETH.MESH.02089392.

<sup>203</sup> ETH.MESH.04099233 (September 24, 2008 email from Melissa Day to Meng Chen and others).

<sup>204</sup> ETH.MESH.03910175-03910177.

**c. Ethicon failed to update the IFU.**

Once TVT was on the market, Ethicon refused to appropriately update the IFU to reflect the known risks above and additional risks. On December 19, 2008, after Dr. Meng Chen had received a complaint from a number of patients about not being fully informed of the risks of the procedure, she recommended to senior management that the IFU be updated:

[The patient] was given the most accurate consent for the potential adverse reaction known in 2005. However, we are in 2008 now, and there are two more TVT family products (TVTO and TVTS) on the market. Our post-market knowledge with these products are much more than what we have in the IFUs of all three types of TVTs (TVT-Abdominal, Obturator and Secur). My reason for bringing this point to you is maybe you may look into it from senior management perspective and to facilitate the IFU update for all three TVTs, particularly in the area of 'Potential Adverse Reactions'.... One of the paths for a better pre-operative consent is to provide an updated IFU to the operating physicians that reflecting the current knowledge of the manufacturer's on the potential adverse reactions."<sup>206</sup>

In a January 29, 2009 email, Meng Chen wrote again that the IFU should be updated to make it clear that the irritation and foreign body response were a result of the tape itself and that this "could result in tape extrusion, tape erosion, fistula formation or inflammation."<sup>207</sup> When working on the Mini-O/Abbrevio IFU, Ethicon employees noted that the older IFU's should be updated. Dr. Aaron Kirkemo wrote:

I would agree from the meeting today that now that we have 12+ years of experience with TVT classic that learnings from the field would probably drive a relook at the TVT Classic IFU as reflected by some of your comments in this document."<sup>208</sup>

In response, Dr. Robison asked: "has there been agreement re: a project to revise TVT and TVTO?"<sup>209</sup> There was indeed agreement at upper management – there would be no revision to

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<sup>205</sup> Weisberg dep. (8/9/13) 968:2-969:10; Robinson Dep. (9/11/13) 329:12-330:7.

<sup>206</sup> ETH.MESH.04092868.

<sup>207</sup> ETH.MESH.04094863 (e-mail from Dr. Meng Chen to Bryan Lisa, Jan. 29, 2009).

<sup>208</sup> ETH.MESH.01239065 at 9066 (July 14, 2009 email from Aaron Kirkemo MD to Piet Hinoul MD and David Robinson MD).

<sup>209</sup> *Id.*

incorporate what they had learned: “Per Scott C and Stale, they just want to “look forward” with this project. Their plans are to leave TVT Classic [and TVT] as is. Aaron.”<sup>210</sup>

Interestingly, in 2008, 2011, 2012, and 2015 Ethicon added numerous adverse reactions and risks to its Patient Brochures that have never been disclosed in previous versions of the Patient Brochures. Some of these adverse reactions and risk have never been disclosed in the TVT IFUs even at present time, and all of these were not in TVT IFUs prior to May, 2015. These risks are as follows:

**From Patient Brochures (never in IFU prior to May, 2015. Those in Yellow are still not in IFU)**

2008

Difficulty urinating Pain

**Scarring**

Mesh Exposure requiring treatment

2011

Mesh exposure into the vaginal canal

Mesh exposure associated with pain during intercourse for the patient and partner

Mesh exposure which may require removal of exposed mesh in office or operating room

2012

Pelvic Pain

Development of Urinary Incontinence

Voiding Difficulties

Hemorrhage or hematoma

Urinary tract infection Wound healing problems Injury to ureters

Pelvic abscess formation

Risk of infection

**Vaginal scarring**

**Mesh contracture (mesh shortening due to scar tissue)**

2015

**Anesthesia risks**

Pain (temporary or chronic)

Seroma

Neuro-muscular problems (including pain in the groin, thigh, leg, pelvic or abdominal area)

Adhesion formation

**Abnormal vaginal discharge**

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<sup>210</sup> *Id.*

Recurrent incontinence

Death

These complications may require additional medical treatment, hospitalization, or surgery

These complications may resolve over time or may be chronic

There is also a risk that the mesh material may erode into another organ such as the bladder or urethra (mesh erosion) and cause pain and additional problems.

Mesh erosion would likely require additional surgery to remove the mesh from the organ.

Some of these risks have been disclosed in Ethicon's other PROLENE mesh IFUs. For example, Ethicon's IFU for PROLENE hernia mesh states as follows: "The use of PROLENE Mesh in contaminated wounds should be with the understanding that subsequent infection may require removal of the material."<sup>211</sup> Even though Ethicon changed its Patient Brochures in 2011 and 2012 to include additional significant adverse events/risks, it never added the same information to the TVT IFU until May of 2015. This is true despite the fact that Ethicon had internal discussions about updating the IFU in 2009 after the 2008 FDA Public Health Notification (PHN). Specifically, a meeting was held to decide, among other issues, whether to update "the current Adverse Reaction of tape exposure and post-operative dyspareunia in the TVT-family products...."<sup>212</sup>

After discussing the 2008 PHN, competitors' labels and Remetrex issues, impressions were that tape exposure/erosion/extrusion were very frequently reported, patients did not feel there were adequate pre-op consent or risk-benefit assessment, patient specific concerns about exposure/erosion/extrusion, incontinence recurrence, post-operative dyspareunia and pain-affect quality of live and affect daily routine, re-operations and post-operative complications disproportionate to pre-operative-consent-expectations.<sup>213</sup> Despite these discussions and Ethicon's scientific knowledge of these serious, devastating and life-changing adverse

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<sup>211</sup> ETH.MESH.02342102.

<sup>212</sup> ETH.MESH 04081189.

events/risks, to this day, it has never updated or changed its IFU to include this information.

Repeatedly, the reason given for not updating an IFU to make it more accurate and safer was that doing so would threaten the launch timing of a new product. For example, when discussing the IFU for TVT-Exact, Dr. David Robinson cautioned against making too many changes from the original TVT-R IFU: “Just to clarify... the more changes we make to the IFU that differ from TVT-Classic, the higher the risk will be to the submission timing.”<sup>214</sup>

In summary, Ethicon did not fully inform physicians about numerous adverse reactions/risks associated with the TVT despite the fact that Ethicon had scientific knowledge of the risks from the time the product was first sold. As a result, physicians were unable to fully consent and inform patients of the risk associated with TVT. In addition, some risks included by Ethicon in the IFU are mischaracterized to minimize the actual risk. Finally, when given numerous opportunities to update the IFU, and in the face of specific requests to do so from numerous medical professionals, Ethicon did not make the necessary updates. To a reasonable degree of medical certainty, this prevented physicians and patients the ability to make an informed choice regarding the use of the TVT. For a surgeon to properly inform the patient of all the known risks involved in any procedure involving an implantable medical device, the surgeon relies upon the manufacturer to have scientific knowledge of and convey all characteristics of its products that could impact safety and efficacy. Specifically, surgeons rely on the “Adverse Events/Risks” section of a medical device IFU to gain scientific knowledge regarding adverse events or undesirable effects that the company knows are associated with the product.

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<sup>213</sup> *Id.*

<sup>214</sup> ETH.MESH.10632650 at 10632652.

**D. The TVT Device Is Not Designed for Special Patient Populations Nor Does the IFU or Marketing Inform Physicians or These Patients of Poorer Outcomes or Higher Risks.**

Ethicon promoted the TVT as a “reproducible” technique that was appropriate for all patients. For example, Ethicon instructed its sales force to specifically target physicians to use the TVT and TVT in obese patients.<sup>215</sup> However, as Ethicon’s Medical Director, Dr. Kirkemo, testified obese patients do not fare well with these devices.

- Q. One of the things that was actually shown in the TVT World study that you worked on was that for obese patients, for example, the efficacy was significantly down when slings were used in obese patients; is that correct?
- A. Obese people tend -- not to do as well.

In fact, Ethicon’s study showed obese patients had about one half the success of those patients who were not obese. In addition, as Dr. Kirkemo testified, obese women suffered from more complications: “Their chance of success goes down. Their risk of complications goes up.”<sup>216</sup>

Yet, Ethicon did not put this critical information into the IFU. Dr. Kirkemo testified:

- Q. Did you ever put that in the IFU?
- A. No....<sup>217</sup>

Not only did Ethicon not put this critical information in the IFU, Ethicon also did not inform patients:

- Q. Did you ever tell patients that in a single patient brochure, that if they were obese, their chances of this being successful were less than half?
- A. We did not.<sup>218</sup>

Ethicon also did not include information in its IFU about how the TVT had less efficacy and higher risk for older women or younger, active women.

- Q. Did you -- you also learned in the TVT World study, or maybe you knew

<sup>215</sup> See, e.g., ETH.MESH.00640394 (trying to convince physicians to use TVT on obese patients); ETH.MESH.05119622 at 9623 (TVT “is a good choice for the obese patient or elderly patient....”).

<sup>216</sup> Kirkemo Dep. (1/7/2014) 556:24-557:1.

<sup>217</sup> Kirkemo Dep. (1/7/2014) 556:4-19.

<sup>218</sup> Kirkemo Dep. (1/7/2014) 557:5-557:9.

- this before, too, that being elderly decreased, or being very young, in fact, decreased the efficacy of the Ethicon sling procedures; correct?
- A. With any incontinence operation, old people tend not to, you know, do as well.
- Q. And was that ever put in a patient brochure or communicated to patients as far as you know?
- A. As near as I can tell, in any marketing document, no.
- Q. And what about the very young or the younger women; that was shown in TVT World that even younger women had lower efficacy; correct?
- A. Some women that are very, very active can -- and have ISD can overcome the effect of the sling.
- Q. In other words, the sling can fail.
- A. The sling can be less than a hundred percent effective.
- Q. And that was never actually communicated to patients as far as you know, correct, by Ethicon?
- A. To my knowledge, no.
- Q. And neither the older women or the younger women in issue we were just talking about, neither of those are included in the IFU; correct?
- A. Those specific things are not mentioned.<sup>219</sup>

Ethicon also did not inform physicians and patients that the TVT devices, including the TVT would not work as well and would be more dangerous for women who smoked or who had Diabetes – a very large percentage of the patients to whom TVT was being marketed:

- Q. Smoking decreases the efficacy of slings; correct?
- A. Yes.
- Q. Diabetes decreases the efficacy of slings; correct?
- A. It can because you have neurologic, you know, disease.
- Q. Neither smoking nor diabetes is listed as a potential contraindication or something special to look for in the IFU; correct?
- A. It is not listed in the IFU....
- Q. And Ethicon never communicated to patients that smoking would increase their risk of adverse outcomes or decrease the chance that the sling would work; correct?
- A. We did not.
- Q. And the same with diabetes. Ethicon never communicated to patients when they were selling TVT devices that diabetes would decrease the chance that the device would work or increase the chance that they would have an adverse event; correct?
- A. I did not see that, no.

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<sup>219</sup> Kirkemo Dep. (1/7/2014) 557:10-558:21.

Ethicon knew that there were other patient populations that also faced increased risk or lower success rates with the TVT. Specifically, Ethicon knew that women who had prior pelvic surgery, prior pelvic injury or an infection, could be at increased risk if undergoing the TVT surgery. In 1999, Ethicon discussed putting another warning in the TVT IFU related to patients who had previous surgeries because of scar tissue.<sup>220</sup> The proposed warning was “patients who have had previous surgical procedures may require special consideration due to scar tissue.”<sup>221</sup> Ethicon was concerned that the risk of mesh extrusion was increased in women with postoperative infection, previous vaginal surgery, vaginal atrophy or vaginal injury.<sup>222</sup> Dr. Isenberg, Ethicon medical director, admitted that if Ethicon knew this, it would have been reasonable to include a warning and, further, physicians and their patients would want to know this information. However, Ethicon was “under extreme pressure” to finish the IFU to meet a scheduled launch date in 1999, so did not include the statement in the April, 1999 IFU update.<sup>223</sup> Ethicon planned to discuss the issue for possible inclusion in the IFU in the future, but I have seen no evidence of such discussion, and this warning never made it into the IFU. Again, despite these discussions in 1999 and former Medical Director Dr. Isenberg’s opinions that it would be reasonable to have this information in the IFU, to this day, this critical information remains absent from the IFU.

Finally, Ethicon also knew that the method of anesthesia utilized during the TVT surgery could affect patients’ outcomes, but didn’t disclose that information to physicians or patients. Ethicon’s internal documents, including interviews with Ethicon’s key opinion leader, Dr. Carl Nilsson, Ethicon U.S. Marketing Research documents, and letters from the inventor of the TVT

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<sup>220</sup> ETH.MESH.08505071, ETH.MESH.00203456, Eth.Mesh.00159634-00159719 at 00159697.

<sup>221</sup> ETH.MESH.08505291.

<sup>222</sup> Id.

<sup>223</sup> ETH.MESH.00203456.

(Dr. Ulmsten) show that Ethicon knew that performing the TVT procedure under general anesthesia as opposed to local anesthesia decreased the chance for success of the surgery and also increased a patient's risk of urinary retention and erosions.<sup>224</sup> This is further supported by the testimony of Dr. Richard Isenberg, a former medical director for Ethicon, who was at Ethicon just after the initial launch of the TVT.<sup>225</sup> Dr. Isenberg testified that the IFU could be better worded so that physicians knew that local anesthesia should be preferred over general anesthesia.<sup>226</sup> In addition, according to Dr. Isenberg, Dr. Ulmsten, inventor of the product, informed Ethicon that the TVT procedure should be carried out under local anesthesia unless it was a special situation.<sup>227</sup> Despite the inventor's desire to have this language listed, to this day, it does not appear in the IFU.<sup>228</sup> Dr. Isenberg was also aware that using general anesthesia could cause the success rate of the procedure to go down and put the patient at increased risk for urinary retention and erosions.<sup>229</sup> He testified that he believes a responsible company should have put this information in the IFU because the IFU is the one document that you can count on every physician receiving.<sup>230</sup> I agree. Again, however, to this day, this warning does not appear in the TVT IFU.

The TVT is dangerous and can cause significant, lifelong injury to women, due in part to its "one-size fits all" design. Ethicon failed to inform physicians that there are certain patient populations that face greater risks and less success with the TVT. Ethicon needed to pass this critical information on to physicians in the IFU so that they could have an appropriate informed consent discussion with their patients.

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<sup>224</sup> Eth.Mesh.04048515-04048520; Eth.Mesh.00130934-00130941, Eth.Mesh. 00400954-00400956.

<sup>225</sup> Isenberg, 11/6/13, 461:16-530:13.

<sup>226</sup> Id. at 526:25-528-18.

<sup>227</sup> Id. at 553:15-554:21.

<sup>228</sup> Id.

<sup>229</sup> Id. at 566:9-15.

<sup>230</sup> Id. at 566:3-8.

Accordingly, it is my opinion to a reasonable degree of medical certainty that the TVT as designed is not effective for special patient populations. In addition, the TVT is dangerous and can cause significant, lifelong injury due in part to its “one-size fits all” design. Moreover, Ethicon failed to inform physicians of the importance of these patient variations and the potential for permanent, serious injury from the TVT. Because Ethicon failed to inform physicians, Ethicon also removed the ability of the physicians to fully inform patients of these risks.

**E. Ethicon failed to reveal material facts about complications and conflict of interests regarding data promoted in the materials.**

Since the TVT was first launched, Ethicon has sent materials in various forms to physicians promoting long term follow up data on the original cohort of patients implanted with the TVT from 1995-1996.<sup>231</sup> Ethicon continued to cite to this data in its TVT materials.<sup>232</sup> In addition, the materials tout low complication rates related to various adverse reactions, including erosions. These materials include press releases, marketing brochures and email blasts.

The long term data primarily relied on by Ethicon throughout these materials relates to the Ulmsten/Nillson studies. These studies were originally started by Dr. Ulmsten, the inventor of the TVT, and continued by Dr. Nillson after Dr. Ulmsten’s death. Prior to selling the TVT to Johnson & Johnson, Dr. Ulmsten owned a company called Medscand. As discussed more fully below, Johnson & Johnson hired Dr. Ulmsten and Medscand to conduct studies related to the TVT. To this day, Ethicon relies heavily on these studies and uses them in numerous promotional materials despite the fact that Ethicon never disclosed to physicians the potential

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<sup>231</sup> ETH.MESH.0015598, ETH.MESH.00658058, ETH.MESH.01186068, ETH.MESH.02236784, ETH.MESH.02237103, ETH.MESH.03459211, ETH.MESH.05183409, ETH.MESH.00339437; ETH.MESH.05794787.

conflict of interest and inherent bias that exists due to Dr. Ulmsten's relationship with Ethicon and Johnson & Johnson. In addition, Ethicon never disclosed to physicians that the device used in the original Medscand study was different than the TVT device. It is important to physicians using the TVT that the data in these types of promotional materials is accurate, unbiased and that physicians are informed about any potential conflicts of interest in the data contained within the materials. In other words, physicians rely on Ethicon to provide fair and balanced information and to ensure that physician have been given all the data and not just the positive press release data.

Despite using the Ulmsten data to promote the TVT, Ethicon never disclosed to physicians the bias and inherent conflict of interest related to the Ulmsten data. Specifically, in its promotional materials, Ethicon (Johnson and Johnson) never informed physicians about its relationship and contracts with Professor Ulmsten and his company Medscand. It is clear from the contracts that the publications and data from Dr. Ulmsten were contracted for hire by Johnson and Johnson International.<sup>233</sup>

The License and Supply Agreement between Johnson and Johnson International and Medscand (Ulmsten's Company) dated February 13, 1997, states in section 3.6 Milestone Payments:

Johnson and Johnson International (JJI) shall pay shall pay to Medscand the following payments (b). A payment in the amount of \$400,000.00 due on February 28, 1997; provided, however, that in the event that Clinical Trials as specified in Exhibit C have not been completed by such date, then such amount shall not be due until the completion of the Clinical Trials.<sup>234</sup>

Under Exhibit F, Consulting Agreement with Professor Alf Ivar Ulmsten, section 4 Confidential Information Rights to Inventions and Copyrights (B) it states:

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<sup>232</sup> ETH.MESH.00163582.

<sup>233</sup> ETH.MESH.08696085 at 085-6134.

Any copyrightable work whether published or unpublished created by supplier Dr. Ulmsten directly as a result of or during the performance of services herein shall be considered a work made for hire, to the fullest extent permitted by law and all rights, titles and interest herein, including worldwide copyrights shall be the property of the company as the employer and party specially commissioned said work.<sup>235</sup>

Finally, in Exhibit C, Clinical Trials, it states:

The results of clinical trials will be considered acceptable if, first, they do not differ significantly from the results published in the original article published in the Int. Urogynecol J 1996-7:81-86 by U. Ulmsten, et.al., with regards to the following items: Safety 1.1, preoperative complications 1.2 , post operative complications 1 year from operation 2. Efficacy. Second Long term results over 1 year from operation do not show a deterioration of rates significantly different from those of the standard suburethral slingplasties. It is assumed that from 12 – 60 months a gradual decrease in efficacy of 5% is normal. 3. No significant numbers of unexpected i.e. not addressed in the original article published in the Int. Urogynecol J 19967 81-86 by U.Ulmsten at et.al. procedure related i.e. not addressed in the review article published in the Int. Urogynecol J 19945: 228-239 by G. N. Ghomiem et.al. complications appear at any time in the postoperative course.<sup>236</sup>

In total, Dr. Ulmsten stood to gain millions of dollars for the 6 papers that he published on the TVT device. In addition, the results of those studies would be found acceptable for payment only if they did not differ from the parameters sent by Johnson & Johnson regarding complications and efficacy. The Ulmsten studies have an inherent conflict of interest and bias as they were “made for hire” and standards were set by Johnson & Johnson. As set forth above, if Dr. Ulmsten did not meet the standards set forth by Johnson & Johnson, he did not receive substantial payments for the “studies.” As a result of this relationship, there is a clear conflict of interest and potential for enormous bias issues.

The conflict of interest and bias created by the relationship between Ethicon and Dr. Ulmsten was acknowledged by Dr. Axel Arnaud, Ethicon’s European Medical Director, in a

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<sup>234</sup> ETH.MESH.08696091.

<sup>235</sup> ETH.MESH.0869116.

<sup>236</sup> ETH.MESH.08696132.

recent deposition. Specifically, Dr. Arnaud testified that such an agreement like the one discussed above between Dr. Ulmsten and Johnson & Johnson creates a potential conflict of interest.<sup>237</sup> Dr. Arnaud also acknowledged that when Johnson & Johnson enters into this type of agreement with a physician or his company and the study is published, there “certainly” needs to be a disclosure of the relationship.<sup>238</sup> Additionally, Former Ethicon Medical Director, Dr. David Robinson, testified that in his experience working in the industry for medical device manufacturers, it is best that potential biases be disclosed.<sup>239</sup> He also testified that if publications from somebody like Ulmsten or Nilsson about safety and efficacy are being published, it is best if they disclose that they have a financial bias or conflict of interest.<sup>240</sup> In fact, in an April 2009 email exchange with Medical Director Piet Hinoul about a physician who, like Ulmsten, is a consultant and inventor for competitor Boston Scientific, Dr. Robinson states that that situation presents “enormous bias issues.”<sup>241</sup> Despite two of its medical directors testifying that the relationship between Ulmsten and carried over to Nilsson presents a conflict of interest and bias, Ethicon has never disclosed this information in its promotional pieces. This is information physicians and patients have a right to know so that a proper informed decision regarding the value of the data in the studies and the use of the product can be made.

Aside from never disclosing to physicians the underlying conflict of interest and bias of the Ulmsten studies in its promotional pieces, Ethicon also never informed them about other problems with the data, including incomplete data on the original cohort, data incorrectly reported and erosion rates underreported. In the original 510k submission for TVT Classic,

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<sup>237</sup> Arnaud Dep. (7/20/13) 497:24-501:21, 509:8-17.

<sup>238</sup> Arnaud Dep. (7/20/13) 514:17-515:1.

<sup>239</sup> Robinson Dep. (9/11/13) 214:15-21.

<sup>240</sup> Robinson Dep. (9/11/12) 215:8-13.

Ethicon used Medscand data from the Scandinavian Multicenter Study.<sup>242</sup> The report shows that 12 month follow was obtained for 90 of the original 131 patients, without explanation of why there was a loss of 41 patients from the study. The study also describes a complication of wound infection: “while the vaginal infection required surgical intervention with resection of exposed mesh.” This represents a vaginal mesh erosion/extrusion/ exposure and needs to be reported as such. However, when the paper was published (Ulmsten, Int Urogynecol J 1998), the paper states that there was no defect healing and no tape rejections. It further misrepresents the outcome for this patient as “The patient with the wound infection had vaginal atrophy. After minimal vaginal wall resection and effective local estrogen treatment she healed without further intervention. There was no tape rejection.”

If Ulmsten had reported a mesh erosion/extrusion/exposure with mesh excision in his study, it would not have been acceptable under Exhibit C of his consulting contract for payment of the \$400,000.<sup>243</sup> This demonstrates that the results of this paper were potentially biased by the payment Ulmsten would receive for favorable data and should discount the data. At the very least, Ethicon should have informed physicians about the relationship between Ethicon and the Ulmsten studies.

Many of the marketing brochures tout the “[t]he urethral erosion rate less than or equal to that of traditional slings; no reported urethral erosions in 10 studies of 50+ patients.”<sup>244</sup> The reference used for the first part of this statement is from Dr. Gary Leach ) who looked at traditional sling procedures done before 1993, when traditional slings were performed at the bladder neck and purposely placed under tension to treat severe stress urinary incontinence

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<sup>241</sup> ETH.MESH.03259439; Robinson Dep. (9/11/13) 219:6-220:10.

<sup>242</sup> ETH.MESH 00371587.

<sup>243</sup> ETH.MESH 08696132.

<sup>244</sup> ETH.MESH 00339439.

from intrinsic sphincter deficiency (particularly among Urogynecologists).

The second part of this statement regarding “no urethral erosions” is incorrect. In published studies, Dr. Karram found one case of urethral erosion in his study of 350 Gynecare TVTs performed (Karram Obstet Gynecol 2003) and Hammad found nine cases of urethral erosion in his study (Hammad Eur Urol 2005).<sup>245</sup> His study followed the complications of 1459 patients 993 of whom had Gynecare TVT, while the remainder has SPARC procedures. While the authors do not break down the incidence of urethral erosion by product, it is exceedingly unlikely that all erosions happen in the SPARC group.

The statement regarding “no urethral erosions” also did not include deTayrac's 2003 paper of 61 patients (31 TVTs) which showed a 3% urethral erosion rate.<sup>246</sup> Dr. Shlomo Raz described a study of 26 patients who presented with voiding dysfunction, including symptoms of severe urethral, pelvic and genital pain, urinary retention, recurrent UTIs, de-novo urgency with urge incontinence found to have mesh from a sling procedure in the bladder or urethra.<sup>247</sup> Their patients were found to have been treated conservatively with anticholinergic medication. They conclude that “dysfunctional voiding symptoms after sling procedure should elicit a high degree of suspicion if pharmacotherapy is not successful in alleviating symptoms...Cystoscopy should be considered if the patient remains symptomatic despite pharmacotherapy.”

In one of the Nilsson studies, Dr. Nilsson describes four patients on “anticholinergics” (Int Urogynecol J 2008 Table 3). They conclude: “It is also encouraging to see that no late adverse effects of the polypropylene tape material was found and that erosion of the tape into

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<sup>245</sup> Karram, M.M., et al., *Complications and untoward effects of the tension-free vaginal tape procedure*, Ob & Gyn 2003, 101:929-32.

<sup>246</sup> de Tayrac, R., et al, *A prospective randomized trial comparing tension-free vaginal tape for surgical treatment of stress urinary incontinence*, Am J Obstet Gynecol 2004, 190:602-8.

<sup>247</sup> Deng D.Y., et al., *Presentation and management of major complications of midurethral slings: Are complications under reported*, Neurourology Urodynamics 2007, 26:46-52.

adjacent tissue did not occur.” However, this statement cannot be made for 4 patients who are on pharmacotherapy without a cystoscopy, which was not performed in the 11 year follow-up study. Dr. Raz’s review of the literature found multiple cases of urethral erosions in a large series with TVT.<sup>248</sup> There have also been multiple case reports attesting to the fact that urethral erosion does occur specifically with Gynecare TVT products.<sup>249</sup> To imply that urethral erosion does not occur is not giving physicians fair and balanced information about the true incidence of urethral erosions with TVT products.

Later, Nilsson publishes the 5 year follow-up of this cohort.<sup>250</sup> He describes the cohort: “a prospective open multicenter trial was conducted in the Nordic countries at the beginning of 1995. The short-term results were published in 1998.” This implies that these are the same patients as published in 1998. It is interesting or an incredible coincidence that the exact number of patients receiving 12 months of follow-up in the Medscand publication (90) was the exact number being described in the 5 year study. There is again no mention of the outcome of the other 41 patients from the original cohort. Another interesting detail in the 5 year study is that the original number of centers used for the study (6) was now down to 3, again without explanation. The 5 year report does describe the original patient with the wound infection but again fails to mention she had mesh excised, “1 case (1.1%) of infection of operating site was observed.”

In 2006, Dr. Nilsson published a different study on long term outcome of patients with

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<sup>248</sup> Karram 2003, Hammad 2005.

<sup>249</sup> Sweat, S., et al, *Polypropylene Mesh Tape for Stress Urinary Incontinence: Complication of Urethral Erosion and Outlet Obstruction*, J Urology 2002, 168:144-146; Gerstenbluth, R.E., et al, *Simultaneous Urethral Erosion of Tension-Free Vaginal Tape and Woven Polyester Pubovaginal Sling*, J Urol. 2003, (2 Pt 1) 170:525-6; Vassallo, B.J., et al., *Management of iatrogenic Vaginal Constriction*, Am J Obstet Gynecol 2003, 102(3):512-20; Haferkamp, A., et al., *Urethral Erosion of Tension-Free Vaginal Tape*, J Urol 2002, 167(1): 250.

<sup>250</sup> Ulmsten data; Nilsson, Int Urogynecol J 2001.

TVT.<sup>251</sup> He describes his new patient population: “A multi-center study comprising only carefully selected primary cases revealed a promising cure rate of 85% after 5 years (reference his 5 year study) and 81% at 7 years.”<sup>252</sup> These two papers are the subject of many press releases and marketing brochures, but they never described that these were carefully selected patients. “To our knowledge, the long-term effect and effectiveness of the TVT procedure has not yet been studied in an unselected patient group. We earlier reported 16-month follow-up results of a general patient group referred to a tertiary medical unit and comprising primary, recurrent, mixed, and low pressure urethra cases. In the present study, we report the long-term results in the same above-mentioned group.” They describe a 3.1% mesh “visualized” rate, half of which needed surgical resection. These results, more representative of what one would see in a normal practice, is never mentioned in press releases or marketing documents.

Conversely, when Ethicon receives adverse information, it does not make it into the promotional pieces. Dr. AC Wang’s abstract, “Tension-Free Vaginal Tape (TVT) for Urinary Stress Incontinence - A Preliminary Report” was used in the original 510k submission in October of 1997 as support for FDA clearance of the TVT.<sup>253</sup> However, when Dr. Wang reported that he had 25 cases of “failure of vaginal healing considered by him to be potential tape rejection...in each case the revision failed within 2 weeks, requiring further surgery to excise mesh and repair the vaginal wound,” this important information never made it into the marketing materials or press releases.<sup>254</sup>

The long-term follow-up data (Ulmsten/Nilsson data) used by Ethicon to promote the lack of risk of TVT is spurious at best. We have incomplete data on the original cohort, data

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<sup>251</sup> Kuuva, N., et al., *Long-term results of the tension-free vaginal tape operation in an unselected group of 129 stress incontinent women*, Acta Obstetrica Gynecologica Scandinavica 2006, 85:4 482-87.

<sup>252</sup> Nilsson, Obstet Gynecol 2004.

<sup>253</sup> ETH.MESH.00371551.

that is falsely reported, original sites that were excluded without explanation and a lead investigator who had a significant relationship and financial incentive to reach certain results with the data. This is the same data which is now used repeatedly in promotional and marketing materials sent to physicians.

**K. The Benefits of the TVT are Outweighed by the Severe, Debilitating and Life Changing Complications Associated with TVT**

It is my opinion, based on my training, experience and extensive review of the literature and Ethicon's internal documents that the benefits of the TVT are outweighed by the severe, debilitating and life changing complications associated with the medical device. It is clear that a substantial number of women who are implanted with the TVT have already and will continue to suffer chronic, debilitating erosions or pain, among other complications, and these life changing complications outweigh the benefits of the TVT, a device used to treat a quality of life issue.

This is especially true given that traditional surgeries like the Burch and pubovaginal slings are not associated with the frequency or extent of these life changing complications. The efficacy of the TVT is equivalent to the traditional surgeries like the Burch. Traditional surgeries are not associated with TVT mesh based complications like contraction and erosion, however, with clinically significant erosion. And, further, although traditional surgeries can cause symptoms such as pain following surgery, including dyspareunia, the risk, duration, extent and severity of chronic pain including dyspareunia following the TVT is much greater than with traditional surgeries, and of course those surgeries do not result in the often untreatable complications and symptoms that result from the TVT mesh.

There were reasonably feasible safer alternatives available to Ethicon for the

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<sup>254</sup> ETH.MESH.00409675.

treatment of patients in this case. For example, the Burch procedure would have been an appropriate treatment for the stress urinary incontinence. The Burch procedure eliminates the risks specifically associated with the old construction heavyweight mesh used in the TVT because the Burch procedure does not require the use of mesh. Another feasible safer alternative to the TVT would have included autologous fascia slings. Sutures used in an alternative design to the TVT (i.e., Burch); an autologous fascial sling; or, an allograft sling (i.e., Repliform) would have been a safer alternative design to the TVT MCM.

Moreover, in this case, because of the injuries suffered by the patient, and because of the manufacturing defect present in the mechanical cut mesh in this case, several additional feasible alternatives were available to Ethicon that would have been less dangerous. As I have testified in previous cases where women have suffered permanent debilitating injuries from TVT mesh products, these alternatives depend on the patient, patient's lifestyle, patient's medical history, and the injuries the patient suffers from. When patients are young and active at the time of surgery, like in this case, and when the mesh contains a manufacturing defect making the mesh especially prone to losing particles, fraying and deformation, like in this case, and because of injuries and risks from the TVT device, certain lighter weight, larger pore mesh resistant to fraying, deformation, shrinkage and particle loss both by design and by improved manufacturing, and include a less invasive implantation method than that used with the TVT would have been less dangerous and a feasible alternative.

In addition, based on Ethicon's internal documents, deposition testimony, and the medical literature, feasible alternatives would have included individually or collectively a lighter weight, larger pore mesh material. Indeed, Ethicon had lighter weight larger pore

meshes that were less stiff and more compliant with patients' tissues that Ethicon marketed for use in the pelvis. A midurethral sling device made from PVDF, (e.g., Dynamesh), or a mesh sling with less polypropylene and sealed edges, or a sling which contained a shorter piece of mesh and had arms consisting of suture like material would have also been a safer alternative.

Additionally, I continue to review internal Ethicon documents and the relevant body of medical literature on a continual basis. I also see women with chronic mesh complications on a continual basis. When I evaluate these women, whether it is in my practice or in a litigation setting, I see life-altering injuries that are related to the type of mesh these women were implanted with, the method in which the mesh was implanted, where the mesh was implanted, but also the patient's lifestyle and makeup. In many of these cases, where one option may be less dangerous for a certain patient, in another patient that same option may be more dangerous. This is because of the unique patient specific concerns that pelvic floor surgeons, like myself, encounter on a daily basis when evaluating medical treatment for specific patients. Indeed, Ethicon and the inventor of the TVT recognized this very concept.

Unfortunately, although there have been a large number of studies and publications involving the TVT over the years, the quality of most of the studies is not good, and the amount of bias included in the studies and publications adds to the limited value that the studies offer about long term, severe and debilitating complications like chronic pain and erosions associated with the TVT. The most recent Cochrane review of mid-urethral slings, Ogah (2011), concluded that most trials involving mid-urethral slings had short follow-up and the quality of evidence was variable such that the quality of evidence for the majority of trials

was moderate with a minority having low-to-moderate evidence.<sup>255</sup> Few trials reported outcomes after 1 year and long term adverse effects had yet to be determined. There are only a handful of RCTs involving the TVT that are long term, and major and long term complications would unlikely be picked up in these RCTs in part because they are designed with a primary endpoint of efficacy, not safety. The true incidence are more likely to be determined by registries or databases, but published registries do not track certain complications such as pain or dyspareunia, and have not been designed to monitor long term problems (Tamussino, 2001 and 2007; Kuuva 2002, Collinet, 2008, Dykorn 2010). This void in studying and presenting the true incidence and nature of long term and life altering complications, along with the biases inherent in many of the studies, and other factors, negates the value of the large majority of the studies, and as a result, other sources of data such as published case series are relevant and important to truly understand the nature of these complications. Ethicon's internal documents and data, which are not publically available, present a very different picture of the TVT than the information that has been shared with patients and physicians.

I have done an in-depth review and analysis of the studies, and am prepared to discuss the studies including the small number of studies that have tracked chronic pain, dyspareunia and erosions on a long term basis. The Abbott study is particularly noteworthy, however. Abbott (2014) described a series of 347 patients evaluated for mesh related complications from 2006 -2010. Approximately 50% had a sling only and an additional 26% had a sling and TVM mesh. The median time from placement to evaluation was 5.8 months with a range of 0 – 65.2. This would mean that many of these patients would not have been captured in registries or RCT's with one year or less follow-up. Also only 26% were seen by another facility before

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<sup>255</sup> Ohah, et. al., Minimally Invasive Synthetic Suburethral Sling Operations for Stress Urinary Incontinence in Women: A Short Version Cochrane Review. *Neurology and Urodynamics* 30:284-291 (2011).

attending one of the study sites, meaning that at least  $\frac{3}{4}$  of these complications were not known to the implanting physician, again highlighting the limited utility of data at the primary site. The authors found 30% of patients had dyspareunia, 43% had erosion and 35% had pelvic pain.<sup>256</sup> This study highlights the degree and severity of the complications that mesh slings like the TVT are causing and, importantly, that physicians in the real world simply do not have the information about the severity of the problem. This is why it is extremely important for manufacturers of slings like Ethicon to accurately and fully report the risks and complications associated with the mesh devices to doctors – something Ethicon simply has not done.

**L. It has been known since the launch of the TVT that the mesh can be difficult to remove, is susceptible to degradation, can rope, curl, deform, fray, and lose particles, and is a heavy weight mesh. However, Ethicon did not account for this facts in its dFMEA at the time of launch, and has failed to complete a proper risk analysis of these hazards**

Ethicon adopted revision 8 of the “Preventia” risk analysis prepared by Medscand AB for the TVT device as part of the TVT design history file.<sup>257</sup> This risk assessment was done on July 12, 2000, and omits numerous risks including that the mesh (1) can be difficult to remove, (2) is susceptible to degradation, (3) can rope, curl, deform (4) fray, and lose particles, and (5) is a heavy weight mesh. Ethicon does not have the previous versions of the risk assessments, revisions 1-7, which would include the version of the risk assessment performed prior to the launch of the TVT in late 1998, but it is reasonable to assume that if these risks had been identified in prior versions, they would still appear in revision 8 dated in July of 2000.<sup>258</sup> In April of 2002, Ethicon identified 11 risks that had been omitted from the Preventia revision 8 risk assessment. These risks include:

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<sup>256</sup> Abbott, et. al., Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study. American Journal of Obstetrics & Gynecology. (Feb. 2014).

<sup>257</sup> ETH.MESH.01317508.

<sup>258</sup> Deposition of Dan Smith, 06-04-2013 794:8-18. Mr. Smith testified that “no person at Ethicon.”

- Vaginal Extrusion
- Erosion/Urethral
- Perforation by Mesh
- Infection
- Vaginal Incision
- Urethral Tear
- Mesh Broken
- Torn Mesh
- Bent Needle
- Mesh Kinked(Twisted)
- Dull Needle

These are all risks that Ethicon knew or should have known at the time of launch of the TVT, and thus should have been assessed prior to launch. Because Ethicon failed to even identify these eleven risks, they also failed to assess the predicted and actual severity and frequency of these events, overall risk score, and actions needed to mitigate the risks of these failures. In addition, Ethicon also failed to identify and assess the other five risks discussed above at the time of launch 1998, or in 2002 when 11 new risks were identified, and still has not conducted a proper risk analysis to this day.

Ethicon clearly did not consider and analyze that TVT mesh (1) can be difficult to remove, (2) is susceptible to degradation, (3) can rope, curl, deform (4) fray, and lose particles, and (5) is a heavy weight mesh as potential failure modes. These were critical analyses in designing and marketing the TVT product and needed to be performed to conduct an appropriate risk analysis and mitigation strategy. There is no mention of these failure modes in the dFMEA in Ethicon's possession at launch, and there has been no proper analysis of these failure modes to this day. It is opinion that Ethicon has failed to meet the standard of care of a reasonable device manufacturer by failing to include these known risks associated with the TVT device on its risk assessments at launch, and has failed to properly assess these known risks to this day.

## V. CONCLUSION.

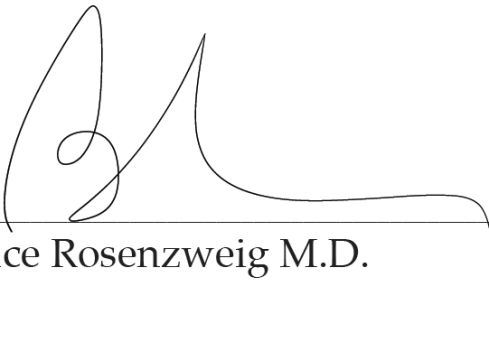
Ethicon has marketed and sold the TVT despite the fact that it contains numerous characteristics that make it unsuitable for implantation in a woman's vagina. These characteristics include the following: (1) degradation of the mesh; (2) chronic foreign body reaction; (3) fraying, sharp edges and particle loss; (4) Infections and Bio-films; (5) roping and curling of the mesh; (6) loss of pore size with tension; (7) fibrotic bridging leading to scar plate formation and mesh encapsulation; and (8) shrinkage/contraction of the encapsulated mesh.

Not only does Ethicon sell a product which should never be put in the vagina, it failed to inform physicians and their patients about numerous risks associated with the product despite the fact that these risks were known before the product was launched. Ethicon has removed the ability of physicians to appropriately inform their patients of the risks and benefits of the TVT and made it impossible for women to consent to the procedure. In addition, despite having knowledge to the contrary, Ethicon never informed physicians and their patients that the TVT could be toxic to their bodies. Finally, while keeping this information from women, Ethicon marketed its product with promotional pieces that did not disclose key conflict of interest information or the true complication rates of its products.

As a result of these failures as fully set forth in this report, the TVT has caused and will continue to cause a multitude of injuries in women, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, nerve injury, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others.

All opinions I have are to a reasonable degree of medical certainty. I understand discovery is still ongoing in this case and I reserve my right to amend my opinions if further information is provided in any form including, but not limited to, corporate documents, depositions and expert reports of both Plaintiff and Defense experts. I have also reviewed the opinions of Dr. Uwe Klinge, Dr. Muhl, Dr. Vladimir Iakovlev, Dr. Elliott, and Dr. Anne Wilson, and incorporate those opinions herein.

Signed this 6th day of January, 2017.

X   
Bruce Rosenzweig M.D.

# **EXHIBIT C**

## DOCUMENTS

Date	Description	Bates - Begin	Bates - End
??/??/09	Stop coping. Start living	ETH.MESH.00002162	ETH.MESH.00002177
1/20/1988	Guidoin Explant Study notes	ETH.MESH.00004755	ETH.MESH.00004755
04/??/08	Klosterhalfen Interim report mesh explants pelvic floor repair	ETH.MESH.00006636	ETH.MESH.00006636
2/6/2009	Haby email re CR Approved 2009-98	ETH.MESH.00007091	ETH.MESH.00007091
	Annotated Prolift +M List of potential claims	ETH.MESH.00008631	ETH.MESH.00008631
	Letter of Proffer: Madigan Army Medical Center	ETH.MESH.00010743	ETH.MESH.00010743
12/8/2003	Attachment V 510(k) Summary Gynecare TVT Obturator	ETH.MESH.00019863	ETH.MESH.00019924
1/16/2002	Luscombe email re ALERT!!! Professional Ads for GYNECARE TVT !!!!! w/attachments	ETH.MESH.00029963	ETH.MESH.00029966
9/27/2002	Letter to Dr. James Meeuwesen of Pueblo, CO from	ETH.MESH.00030025	ETH.MESH.00030026
5/13/2003	Memo from Anthony Powell (VP, Sales) and	ETH.MESH.00030098	ETH.MESH.00030098
7/7/2003	Email Brian Luscombe re "Urethral erosion may occur with any sling material" Article (TVT063)	ETH.MESH.00030372	ETH.MESH.00030373
10/7/2004	Sales School Presentation: Gynecare Professional Relations and Professional Education "Educating	ETH.MESH.00031538	ETH.MESH.00031560
	Prolift - Level One Mesh Course	ETH.MESH.00057142	ETH.MESH.00057146
6/4/2008	Linton email re AUGS attendees	ETH.MESH.00057335	ETH.MESH.00057335
2/19/2008	Pelvic Floor Summit	ETH.MESH.00057336	ETH.MESH.00057374
4/20/2009	Chaves M email chain re CR Approved 2009-471 What's Left Behind Abbrevio	ETH.MESH.00057513	ETH.MESH.00057514
	Franco Naples, FL Presentation - The Science of "What's Left Behind" . . .	ETH.MESH.00057515	ETH.MESH.00057531
	Voicemail from Kevin Mahar to EWH&U Sales & Marketing Organization re FDA PHN Product defect	ETH.MESH.00066960	ETH.MESH.00066960
2/25/2010	Robinson D email chain re 510k submission and clearance	ETH.MESH.00073089	ETH.MESH.00073093
3/10/2010	Savidge S and Johnson L - biocompatibility statement	ETH.MESH.00074068	ETH.MESH.00074070
	Presentation: Gynecare Prolift+M Pelvic Floor Repair System Training	ETH.MESH.00074499	ETH.MESH.00074499
1/5/2010	Timoner Fortin, S email chain re Prosima learning's at preceptor sites EMEA	ETH.MESH.00077727	ETH.MESH.00077732
7/30/1998	Kaminski Memo re summary of key point from US Marketing Research Study on TVT	ETH.MESH.00130934	ETH.MESH.00130941
3/1/2006	Mahar email chain re Urgent Request: Revised TVt Complication data 2-9-06	ETH.MESH.00134029	ETH.MESH.00134031
1/15/2006	Miller email chain re GYNECARE TVT Latest Complication Data	ETH.MESH.00134498	ETH.MESH.00134499

## DOCUMENTS

Date	Description	Bates - Begin	Bates - End
5/11/2007	Email Price St. Hilaire to Dr Kavalier re AUA in Booth Activities	ETH.MESH.00136359	ETH.MESH.00136359
7/1/2009	AdvaMed Code of Ethics on Interactions with Healthcare Professionals	ETH.MESH.00139845	ETH.MESH.00139867
	Feeney letter re Secondary Sales School #7	ETH.MESH.00140431	ETH.MESH.00140452
9/22/2000	Memo from J.L. Toth to Copy Review Team re "A three-year follow up of tension free vaginal tape for surgical treatment of the female stress urinary incontinence" Article (TVTO15 - REVIEW FOR REPRINT	ETH.MESH.00143697	ETH.MESH.00143699
9/22/2000	Memo from J.L. Toth to Copy Review Team re "A three-year follow up of tension free vaginal tape for surgical treatment of the female stress urinary incontinence" Article (TVTO15 - REVIEW FOR REPRINT	ETH.MESH.00143700	ETH.MESH.00143702
	Presentation draft - Tension-Free Support for Female SUI (258 Patients) - Modarelli, et al	ETH.MESH.00143842	ETH.MESH.00143842
6/7/2001	TVT 20010607 Gynecare TVT Tension-free Support for Incontinence	ETH.MESH.00144270	ETH.MESH.00144278
7/3/2001	Presentation: TVT Sales Force Update @ Divisional Meeting	ETH.MESH.00144304	ETH.MESH.00144331
	7 year Data Press Release - New Study Shows Minimally-Invasive Surgery for Female Incontinence Offers Good Long-Term Cure Rates	ETH.MESH.00155598	ETH.MESH.00155600
4/19/2004	LIMS Project #: BE-2004-912 Study Report	ETH.MESH.00158286	ETH.MESH.00158288
8/14/2000	TVT Professional Education Tensioning	ETH.MESH.00158559	ETH.MESH.00158590
	Toth Memo w/ Gynecare TVT Professional Education Slides	ETH.MESH.00159634	ETH.MESH.00159719
6/9/2000	Toth Memo re Gynecare TVT Tension-free Support for Incontinence Patient Education Brochure (TVT016)	ETH.MESH.00160612	ETH.MESH.00160625
1/1/2004	Only Gynecare TVT Has Long-term Results You Can See	ETH.MESH.00160813	ETH.MESH.00160821
4/11/2001	Toth Memo re Gynecare TVT Tension-free Support for Incontinence Competitive Mesh Products - Product Pointer	ETH.MESH.00161129	ETH.MESH.00161130
4/17/2001	Product Pointer: Gynecare TVT Tension-free Support for Incontinence: A Synthetic Sling with Erosion Rates No Higher Than Autologous Slings	ETH.MESH.00161131	ETH.MESH.00161132
	TVT Detail Sheet (TVTOO1R	ETH.MESH.00161444	ETH.MESH.00161445
1/2/2007	TVT sales piece (TVTS004)	ETH.MESH.00161512	ETH.MESH.00161513
2/2/2005	TVT Mailers for Physicians	ETH.MESH.00162420	ETH.MESH.00162421
??/??/07	Brochure "Find out how to stop urine leakage like Bonnie did"	ETH.MESH.00163582	ETH.MESH.00163597

## DOCUMENTS

Date	Description	Bates - Begin	Bates - End
	Final FDA Notification about Use of Surgical Mesh to Treat Pelvic Organ Prolapse and Stress Urinary Incontinence Standby for Media/Analyst inquiries	ETH.MESH.00164023	ETH.MESH.00164025
9/25/2008	TVT sales piece	ETH.MESH.00164643	ETH.MESH.00164648
7/25/2007	Physician Brochure TVTS001RS - TVT SECUR System	ETH.MESH.00166287	ETH.MESH.00166292
4/18/2006	CER Weisberg - Laser Cut Mesh	ETH.MESH.00167104	ETH.MESH.00167110
6/26/2006	Product Pointer: Gynecare TVT Tension-free Support for Incontinence -- available in laser cut mesh	ETH.MESH.00167119	ETH.MESH.00167119
3/22/2006	TVT Slim Jim (TVT107)	ETH.MESH.00169748	ETH.MESH.00169751
6/8/2011	O'Connell email chain re Articles of Mesh Properties	ETH.MESH.00185184	ETH.MESH.00185184
3/30/1999	Gillick email chain re TVT insert	ETH.MESH.00203456	ETH.MESH.00203456
2/28/2011	Gauld email re Here is the copy of FDA's letter (please do not forward)	ETH.MESH.00206973	ETH.MESH.00206973
2/11/2011	Letter from Pollard to Lin, date-stampede K103727 Trade Name: GYNECARE TVTO-PA Continence System	ETH.MESH.00206974	ETH.MESH.00206981
2/25/2010	Pruden G email chain re Concerns raised re TVT Abbrevio surgical procedure	ETH.MESH.00207012	ETH.MESH.00207015
	Team conference call notes	ETH.MESH.00208897	ETH.MESH.00208897
9/22/2009	Hinoul P email chain re TVTO mini IFU rewrite	ETH.MESH.00209295	ETH.MESH.00209299
10/7/2009	Email Sandy Savidge to Katrin Elbert re TVTO mini IFU rewrite	ETH.MESH.00209965	ETH.MESH.00209968
	Mini TVT-O Team Meeting Agenda	ETH.MESH.00211038	ETH.MESH.00211041
	Email Sandy Savidge to Donna Taggart re TVT EXACT IFU Proof Read 9/14/09	ETH.MESH.00211259	ETH.MESH.00211260
	Email Susan Lin re TVT EXACT IFU Proof Read 9/14/09	ETH.MESH.00211263	ETH.MESH.00211265
3/25/2010	Draft TVT Family strategic positioning overview presentation	ETH.MESH.00212665	ETH.MESH.00212665
12/9/2003	3.4.4 DDSA version 0 - Memo Gary Borkes to DHF for the Gynecare TVT-Obturator re TVT-O Version 0 Design Risk Assessment Evaluation	ETH.MESH.00222366	ETH.MESH.00222395
5/14/2001	TVT-O Design History Book 5 of 7	ETH.MESH.00222779	ETH.MESH.00223267
	DHF0000747 TVT Retropublic Refresh	ETH.MESH.00223634	ETH.MESH.00223655
	Spreadsheet TVT Retropublic Refresh	ETH.MESH.00223640	ETH.MESH.00223640
	Powerpoint TVT Retropublic Refresh	ETH.MESH.00223800	ETH.MESH.00223800
4/14/2010	TVT Retropublic Refresh	ETH.MESH.00223801	ETH.MESH.00223828
5/14/2001	TVT-O Design History Book 1 of 7	ETH.MESH.00259047	ETH.MESH.00259514
	Design Input Strategy Project Mulberry by Dan Smith	ETH.MESH.00259269	ETH.MESH.00259274

Date	Description	Bates - Begin	Bates - End
	Clinical Expert Report - Weisberg Assessment of the "inside-Out" Transobturator Approach to Implant . . .	ETH.MESH.00259634	ETH.MESH.00259644
4/14/2003	Smith,D email chain re Mulberry update	ETH.MESH.00260591	ETH.MESH.00260592
8/15/2003	Email Brian Luscombe re Mulberry Final DRAFT #1	ETH.MESH.00260739	ETH.MESH.00260744
1/11/2005	Email Katrin Elbert re TVT-O IFU change	ETH.MESH.00261818	ETH.MESH.00261818
??/??/10	The efficacy she needs with less mesh - TVT Abbrevio	ETH.MESH.00270802	ETH.MESH.00270821
	Franco presentation - The Science of "What's Left Behind" . . . Evidence & Follow-Up of Mesh Use for SUI	ETH.MESH.00271641	ETH.MESH.00271641
7/29/2011	Email Vijay Madikonda re BSI Technical File Audit - July 28-29, 2011	ETH.MESH.00301367	ETH.MESH.00301369
	Lamont email chain re !!!!Great News for TVT Laser Cut Mesh!!!!	ETH.MESH.00301741	ETH.MESH.00301742
	TVT Laser Cut Mesh Project Revision History for DFMEA0000242	ETH.MESH.00301977	ETH.MESH.00301977
2/24/2006	Lamont D Memo re TVT Laser Cut Mesh Risk Analysis Summary	ETH.MESH.00302105	ETH.MESH.00302106
3/29/2006	Email Daniel Lamont to Jacqueline Flatow re TVT LCM - design inputs	ETH.MESH.00302181	ETH.MESH.00302184
2/23/2006	Memo Dan Lamont re TVT-Base & TVT-O Complaint Review for Laser Cut Mesh (LCM) Risk Analysis	ETH.MESH.00302390	ETH.MESH.00302392
2/20/2007	Lamont D email chain re Complaint Summaries	ETH.MESH.00303084	ETH.MESH.00303085
3/5/2008	Lamont D email chain re Gynemesh issue	ETH.MESH.00303944	ETH.MESH.00303945
4/29/2008	Lamont D email chain re Post Launch Reviews	ETH.MESH.00304013	ETH.MESH.00304014
	Maree, A email chain re AUSA update and telephone call with Prof Frazer	ETH.MESH.00311792	ETH.MESH.00311794
7/20/2006	Email Paula Evans to David Robinson et al. re TVT dataMcNelis, Linda	ETH.MESH.00311802	ETH.MESH.00311804
	Presentation: Investigator Initiated Study Process by Kimberly Hunsicker, MSN, CRNP Regional Manager, Clinical Operations	ETH.MESH.00311832	ETH.MESH.00311848
11/2/2007	Beath email chain re Meeting with the Australian Regulator to discuss TVT Secur performance	ETH.MESH.00312179	ETH.MESH.00312182
01/??/08	Working copy - Communications to Surgeons re TVT SECUR	ETH.MESH.00318311	ETH.MESH.00318312
	Manley email chain re Project priorities for WH&U #1 TVT-Secur, #2 Laser cut TVT #3 Mint, #4 PROFIX	ETH.MESH.00321229	ETH.MESH.00321230
	Definition for Major Invasive Surgeries and The Ethicon Franchise Products Requiring Major Invasive Procedures for Implantation	ETH.MESH.00321804	ETH.MESH.00321805

## DOCUMENTS

Date	Description	Bates - Begin	Bates - End
11/3/2007	Robinson email chain re URGENT: Meeting with the Australian Regulator to discuss TVT Secur performance	ETH.MESH.00326865	ETH.MESH.00326870
	Yale email chain re TVT-S Update	ETH.MESH.00326882	ETH.MESH.00326884
3/3/2008	Robinson D email chain re Quality issue with a batch of gynemesh	ETH.MESH.00328895	ETH.MESH.00328901
	Email Jennifer Paine to Catherine Beath, et al. re FDA Public Health Notice on Surgical Mesh for POP and SUI - URGENT	ETH.MESH.00329112	ETH.MESH.00329113
2/23/2006	Email Cindy Crosby to Mark Yale, et al. re MHRA request - TVT blue pigment risk assessment	ETH.MESH.00330760	ETH.MESH.00330764
3/11/2009	Physican brochure/sales aid "Make Data and Safety your Choice"	ETH.MESH.00339053	ETH.MESH.00339057
	Lisa B email chain re TVT Patient Brochure Fair Balance EPI Changes	ETH.MESH.00339083	ETH.MESH.00339084
02/??/02	5 Years of Proven Performance TVT Sales Aid (TVT041)	ETH.MESH.00339437	ETH.MESH.00339442
	Spreadsheet DFMEA's TVT Classic	ETH.MESH.00340835	ETH.MESH.00340835
??/??/02	CER Update for TVT	ETH.MESH.00340836	ETH.MESH.00340838
2/17/2010	Gynecare TVT Device Instructions for Use Revision Design Verification Memo by Kirkemo, Robinson and Hinoul	ETH.MESH.00340839	ETH.MESH.00340839
1/8/2010	Global Regulatory Strategy for TVT IFU (RMC P15506/E) Update (Part II, RA0001-2010, Rev. 0) by Susan Lin to John Young	ETH.MESH.00340990	ETH.MESH.00340999
7/1/2010	TVT-Abbrevo FDA communication and 510k	ETH.MESH.00343129	ETH.MESH.00343225
??/??/10	Draft 510(k) premarket Abbrevo	ETH.MESH.00343379	ETH.MESH.00343442
5/16/2008	Email Krystina Laguna to Price St. Hilaire re Copy Review TVT Complications	ETH.MESH.00345289	ETH.MESH.00345291
??/??/09	Mini TVT-O Claim Development	ETH.MESH.00345842	ETH.MESH.00345842
6/29/2010	Lisa B email re TVT Abbrevo claims support	ETH.MESH.00346157	ETH.MESH.00346157
??/??/10	The efficacy she needs with less mesh - annotated - round 3	ETH.MESH.00346194	ETH.MESH.00346201
4/1/2009	Lisa B email re TVT-Mini clinical support	ETH.MESH.00346227	ETH.MESH.00346227
	Hinoul P, Synopsis of preclinical data in support of TVT Abbrevo's equivalence to TVT-O	ETH.MESH.00346427	ETH.MESH.00346439
07/??/12	Claims for Gynecare TVT Abbrevo spreadsheet	ETH.MESH.00346665	ETH.MESH.00346667
	Spreadsheet TVT Secur dFMEA Rev #1	ETH.MESH.00349122	ETH.MESH.00349122
1/27/2010	TVT ad "Demand the most proven technology when selecting a mid-urethral sling... Make DATA and SAFETY YOUR CHOICE"	ETH.MESH.00349508	ETH.MESH.00349512
	Abbrevo FAQs -	ETH.MESH.00350696	ETH.MESH.00350696
2/24/2010	Gauld J email chain re TVT-Abbrevo	ETH.MESH.00350720	ETH.MESH.00350720
3/23/2010	Smith D email chain re Input to the one-pager to BR	ETH.MESH.00351439	ETH.MESH.00351441

## DOCUMENTS

Date	Description	Bates - Begin	Bates - End
3/16/2010	Savidge S email chain re First draft equivalence Abbrevio	ETH.MESH.00351697	ETH.MESH.00351701
	Annotated Slide	ETH.MESH.00353476	ETH.MESH.00353476
	Linn email chain re Exception request for Abbrevio Professional education deck	ETH.MESH.00354234	ETH.MESH.00354234
	Spreadsheet DFMEA's re TVT-O pain	ETH.MESH.00354724	ETH.MESH.00354724
	Spreadsheet DFMEA's re TVT-O pain	ETH.MESH.00354725	ETH.MESH.00354725
6/6/2008	Nilsson, et al. "Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence"	ETH.MESH.00355003	ETH.MESH.00355007
	Differentiation Statement	ETH.MESH.00355435	ETH.MESH.00355435
1/28/1998	FDA 510(k) clearance letter	ETH.MESH.00371496	ETH.MESH.00371594
1/1/1997	Alex C. Wang "Tension-Free Vaginal Tape (TVT) for Urinary Stress Incontinence - A Preliminary Report"	ETH.MESH.00371572	ETH.MESH.00371573
	Eriksson Clinical Report	ETH.MESH.00371587	ETH.MESH.00371594
2/1/2006	Global Regulatory Strategy GYNECARE TVT - Laser Cutting Project	ETH.MESH.00394544	ETH.MESH.00394553
	Review of Surgical Techniques Using Mesh, Robinson presentation	ETH.MESH.00396836	ETH.MESH.00396868
	Ulmsten letter to Rick	ETH.MESH.00400954	ETH.MESH.00400956
06/??/00	TVT Surgeons Resource Monograph	ETH.MESH.00400957	ETH.MESH.00400978
	Clinical Study Agreement between Dr. Douglas Grier and Ethicon	ETH.MESH.00401213	ETH.MESH.00401217
3/20/2009	Letter Patricia Beach (Ethicon) to Dr. Douglas Grier re TVT World Registry	ETH.MESH.00407285	ETH.MESH.00407285
10/4/2002	Rejection of Polypropylene Tape After the Tension-Free Vaginal Tape (TVT) Procedure by Alex C. Wang, MD	ETH.MESH.00409657	ETH.MESH.00409658
	Customer Initiated Research Grant Request (Wang)	ETH.MESH.00409659	ETH.MESH.00409663
12/3/2002	Email Martin Weisberg to Mark Sumeray et al. re Prolene rejection	ETH.MESH.00409670	ETH.MESH.00409670
6/7/2002	Email Richard Isenberg to Greg Jones, et al. re Dr Alex Wang, Taiwan--Reports of "tape rejection" with TVT	ETH.MESH.00409674	ETH.MESH.00409675
7/19/2005	Clinical Study Agreement between Dr. Douglas Grier and Ethicon	ETH.MESH.00412260	ETH.MESH.00412269
	Zipfel R email re Anhalt - NY Times article - Trial of Synthetic Mesh in Pelvic Surgery Ends Early	ETH.MESH.00427910	ETH.MESH.00427910
1/5/2005	Email Laura Angelini to Ronnie Toddywala, et al. re Important Laser cut mesh Update	ETH.MESH.00440005	ETH.MESH.00440007
5/28/2010	Consulting Agreement Requisition Form between Brian J. Flynn and Ethicon	ETH.MESH.00493332	ETH.MESH.00493343

## DOCUMENTS

Date	Description	Bates - Begin	Bates - End
??/??/10	2010 preceptor payments spreadsheet	ETH.MESH.00499024	ETH.MESH.00499024
10/9/2006	Email Cheryl Bogardus to Dharini Amin re TVT 10 year anniversary/10 year data from Nillson	ETH.MESH.00524059	ETH.MESH.00524060
	Letter from Martin Weisberg re 7 Year Data Indicates Strong Continued Safety and Effectiveness for Gynecare TVT Tension-free Support for Incontinence	ETH.MESH.00524444	ETH.MESH.00524445
2/1/2005	Presentation: TVT Bonnie Blair Campaign	ETH.MESH.00524907	ETH.MESH.00524907
8/24/2005	Gynecare TVT Professional Education Slides	ETH.MESH.00525322	ETH.MESH.00525400
8/16/2005	London Brown A email re TVT Laser Cut Mesh	ETH.MESH.00525573	ETH.MESH.00525573
5/6/2005	London Brown A email re Laser-cut Mesh	ETH.MESH.00526473	ETH.MESH.00526474
6/23/2006	St. Hilaire P email chain re LCM - Launch Strategy EMEA	ETH.MESH.00526484	ETH.MESH.00526487
	Product Quality Plan for Gynecare Gynemesh XL	ETH.MESH.00528636	ETH.MESH.00528641
08/??/09	HS Study Monthly Update	ETH.MESH.00533025	ETH.MESH.00533026
4/28/2009	TVT-World-Wide Observational Registry for Long-Term Data	ETH.MESH.00533250	ETH.MESH.00533256
9/29/2009	Communication Plan to close TVT World Registry	ETH.MESH.00533283	ETH.MESH.00533286
3/20/2007	TVT-World-Wide Observational Registry for Long-Term Data	ETH.MESH.00539862	ETH.MESH.00539898
	Monthly Complaint Review November 2010	ETH.MESH.00540449	ETH.MESH.00540449
4/19/2011	Monthly Complaint Review	ETH.MESH.00540629	ETH.MESH.00540629
	Weisberg Memo re Mesh Fraying for TVT Devices	ETH.MESH.00541379	ETH.MESH.00541380
4/19/2010	Waltregny D email chain re Your Submission	ETH.MESH.00574783	ETH.MESH.00574783
3/8/2011	Papas N email chain re AUGS abstract	ETH.MESH.00575160	ETH.MESH.00575161
3/2/2011	Hinoul email re Laser cut mesh tape	ETH.MESH.00576844	ETH.MESH.00576845
	Annotated - Evaluation of the Fixation of TVT Abbrevio as compared to TVT-O in a Human Cadaveric Model	ETH.MESH.00576887	ETH.MESH.00576888
3/18/2003	Osoris M email re International Convention Suggestions	ETH.MESH.00581482	ETH.MESH.00581482
	Gynecare International Convention Recommendations	ETH.MESH.00581483	ETH.MESH.00581486
5/22/2006	Sungyoon Rha email re First Human Use - Surgeon preference Questionnaire	ETH.MESH.00584175	ETH.MESH.00584178
2/3/2014	Mesh Slide T-3581	ETH.MESH.00584179	ETH.MESH.00584179
2/15/2006	Flatow J email chain re DVer protocol for particle loss	ETH.MESH.00584291	ETH.MESH.00584292
8/29/2006	Second half photo presentation. ppt	ETH.MESH.00584527	ETH.MESH.00584527
4/19/2004	Kammerer G email re Ultrasonic Slitting of Prolene Mesh for TVT	ETH.MESH.00584811	ETH.MESH.00584813
1/17/2005	Kammerer email re Presentation #1	ETH.MESH.00585220	ETH.MESH.00585220
3/10/2006	Next Generation Mesh Discussion Agenda	ETH.MESH.00585672	ETH.MESH.00585673

## DOCUMENTS

Date	Description	Bates - Begin	Bates - End
5/9/2006	Kammerer G email re Particle loss of TVT	ETH.MESH.00585802	ETH.MESH.00585802
6/27/2006	Kammerer email chain re Urgent *** French Standard on TVT & Meshes (Comments Required)	ETH.MESH.00585823	ETH.MESH.00585832
6/27/2006	Kammerer email chain re URGENT French STANDARD ON TVT & Meshes	ETH.MESH.00585823	ETH.MESH.00585832
6/12/2006	Kammerer G email chain re TVT LCM - particle loss (reimbursement submission)	ETH.MESH.00585842	ETH.MESH.00585843
6/19/2003	Eltrasonic Slitting of TVT Mesh presentation	ETH.MESH.00586018	ETH.MESH.00586019
	Silimkhan presentation Evaluation of Gynecare Prolene Meshes	ETH.MESH.00586019	ETH.MESH.00586019
	Spreadsheet DFMEA's TVT Classic	ETH.MESH.00589494	ETH.MESH.00589494
3/11/2009	Hinoul P email re EJOGB-08-4159R1 - Minor Revision	ETH.MESH.00590896	ETH.MESH.00590897
4/8/2009	Hinoul email chain re registry for all!	ETH.MESH.00591127	ETH.MESH.00591128
9/14/2009	Savidge S email chain re TVT RR IFU 090911b_T-3467	ETH.MESH.00592915	ETH.MESH.00592916
3/23/2010	Kirkemo A email re Meeting with Bridget O Transformation nature of Scion delivery system	ETH.MESH.00600985	ETH.MESH.00600987
4/7/2010	Robinson D email re Please hold: database study vendor selection	ETH.MESH.00602025	ETH.MESH.00602027
3/10/2010	Kirkemo A email re Scion PA commercial recommendation	ETH.MESH.00607406	ETH.MESH.00607410
	U.S. Launch Overview	ETH.MESH.00632655	ETH.MESH.00632655
	Gynecare TVT Sales Representative quick reference sheet	ETH.MESH.00640394	ETH.MESH.00640395
	Robinson email chain re TVT ) versus TVT Secur efficacy and safety rates	ETH.MESH.00647404	ETH.MESH.00647409
4/14/2004	TVT sales piece (TVT041R3)	ETH.MESH.00658058	ETH.MESH.00658065
6/1/2000	Surgeon's Resource Monograph	ETH.MESH.00658177	ETH.MESH.00658198
4/13/2005	TVT 20040413 Gynecare TVT Tension-free Support for Incontinence Patient Education Brochure/Robin Osman	ETH.MESH.00658421	ETH.MESH.00658429
??/??/08	Brochure The Gynecare TVT Family of Products 3 SUI Solutions. Delivering Data, Safety & Choice.	ETH.MESH.00658453	ETH.MESH.00658458
2/26/2010	Physician brochure/sales aid	ETH.MESH.00659430	ETH.MESH.00659431
9/7/2004	Walji email chain re Pelvic Floor Monthly - August Report - Next Gen Materials Progress	ETH.MESH.00681364	ETH.MESH.00681366
	Mahar K mail chain re Lazer cut mesh	ETH.MESH.00687819	ETH.MESH.00687822
	Honjnoski P email chain re CER - LCM	ETH.MESH.00700344	ETH.MESH.00700345
3/30/2006	Gadot email chain re Laser Cut Mesh Positioning (Redacted)	ETH.MESH.00700348	ETH.MESH.00700350
10/4/2006	Mahar email chain re TVT LCM Early EU Feedback	ETH.MESH.00708571	ETH.MESH.00708576

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Date	Description	Bates - Begin	Bates - End
	Mahar email chain re Continued Positive Feedback on LCM from EMEA - Rep Survey & Customer Guarantee attached	ETH.MESH.00708653	ETH.MESH.00708655
2/6/2007	Mahar email chain re hospital concern from medico-legal standpoint	ETH.MESH.00719198	ETH.MESH.00719209
2/6/2007	St. Hilaire email chain re OBGYN Department Members. Due to the potential serious implications . . .	ETH.MESH.00722339	ETH.MESH.00722349
10/4/2006	Hernandez email chain re TVT LCM Early EU Feedback	ETH.MESH.00746204	ETH.MESH.00746208
10/4/2006	Hernandez J email re TVT LCM Early EU Feedback	ETH.MESH.00746204	ETH.MESH.00746208
??/??/06	Product Pointer	ETH.MESH.00746209	ETH.MESH.00746209
	Product Pointer Gynecare TVT	ETH.MESH.00746209	ETH.MESH.00746209
	Surgeon Evaluation Questions for Laser Cut Mesh	ETH.MESH.00746210	ETH.MESH.00746212
	Spreadsheet DFMEA's TVT Classic	ETH.MESH.00748275	ETH.MESH.00748275
	K012628 TVT Blue System and Accessory TVT-AA	ETH.MESH.00748310	ETH.MESH.00748450
4/28/2010	TVT Family of Products Co-positioning EWHU Board Pre-Reading	ETH.MESH.00750880	ETH.MESH.00750881
9/2/2010	EWHU Incontinence EWHU Board Meeting Presentation - TVTO version 3	ETH.MESH.00751159	ETH.MESH.00751159
	abbrevo afmea rev a	ETH.MESH.00754439	ETH.MESH.00754439
1/15/2006	Email Dennis Miller to Dharini Amin et al. re Gynecare TVT Latest Complication Data	ETH.MESH.00756887	ETH.MESH.00756888
	Email David Robinson to Giselle Bonet re forgot	ETH.MESH.00756984	ETH.MESH.00756984
9/11/2009	Mini TVT-O Stage Gate: Charter presentation	ETH.MESH.00758412	ETH.MESH.00758412
6/11/2003	Russo-Jankewicz email re Stressful Secrets press release crosses wire	ETH.MESH.00764215	ETH.MESH.00764216
8/2/2001	5-Year Press Release Draft: Long-term Data Proves Safety and Efficacy of GYNECARE TVT Tension-free Support Treating Stress Urinary Incontinence	ETH.MESH.00764323	ETH.MESH.00764325
	Memo to Jacqueline Russo from Ogilvy Public Relations	ETH.MESH.00766347	ETH.MESH.00766349
1/27/2003	DTC Focus Group Summary	ETH.MESH.00766975	ETH.MESH.00766976
	Osman R email chain re 2008 Budget Spend	ETH.MESH.00772228	ETH.MESH.00772229
	Osman R email chain re Updated Fair Balance for TVT Brochure	ETH.MESH.00772231	ETH.MESH.00772232
2/27/2006	Bonet email re Prolift Anatomy Images	ETH.MESH.00782152	ETH.MESH.00782152
??/??/11	Competitive Dissection Flashcard	ETH.MESH.00790545	ETH.MESH.00790546
1/20/2011	PowerPoint - Physician Survey Results January 20, 2011	ETH.MESH.00791766	ETH.MESH.00791813
10/1/2010	Flax C email chain re TVT Abbrevo material	ETH.MESH.00796051	ETH.MESH.00796052

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	Email from David Robinson (Medical Director) re Risk/Benefit Analysis for TVT SECUR Clinical Expert Report	ETH.MESH.00823660	ETH.MESH.00823660
8/11/2010	Hinoul P email re CER Abbrevio	ETH.MESH.00826026	ETH.MESH.00826027
8/11/2010	Hinoul Clinical Expert Report	ETH.MESH.00826028	ETH.MESH.00826045
	Product Complaints Graph	ETH.MESH.00826046	ETH.MESH.00826047
3/2/2009	Hernandez J email chain re EWHU Board recommendation	ETH.MESH.00827376	ETH.MESH.00827379
2/26/2007	Emails from David Robinson re modified version of TVT-O[TOT] procedure	ETH.MESH.00832937	ETH.MESH.00832939
8/31/2007	Robinson D email Chain re Asking TVT Complication? - Fraying	ETH.MESH.00844341	ETH.MESH.00844344
2/28/2006	Robinson email re tvf - training	ETH.MESH.00846523	ETH.MESH.00846523
2/6/2006	Robinson email chain re TVT complications	ETH.MESH.00847536	ETH.MESH.00847536
1/22/2004	Presentation: Sales Training Launch Meeting Gynecare TVT Obturator System	ETH.MESH.00857821	ETH.MESH.00857923
	Smith D Memo re Gynecare Board risk discussion before launch	ETH.MESH.00858080	ETH.MESH.00858081
4/10/2003	April 10, 2003 meeting minutes from Project Leader Dan Smith	ETH.MESH.00858110	ETH.MESH.00858111
	London Brown Memo to Smith re Mechanical Cut vs Laser Cut Mesh Rationale	ETH.MESH.00858252	ETH.MESH.00858253
	TVT Products Flowchart	ETH.MESH.00858891	ETH.MESH.00858891
4/27/2004	LIMS Project #: BE-2004-916	ETH.MESH.00862206	ETH.MESH.00862208
	PT0-0746; Version 1 Validation Protocol for Knitting, Scouring and Heat-Setting 6-mil Old Construction Blue PROLENE Mesh at Secant Medical	ETH.MESH.00862227	ETH.MESH.00862235
	MS729-XXX;Appendix 1	ETH.MESH.00862284	ETH.MESH.00862289
2/27/2004	Smith D email chain re 2 TVT Complaints concerning allegedly brittle mesh	ETH.MESH.00863391	ETH.MESH.00863393
3/9/2004	Luscombe B email chain re Complaint TVT-O	ETH.MESH.00863405	ETH.MESH.00863407
6/30/2004	Leibowitz email re Comparison of TVT Mesh to Meshes from Competitive Devices	ETH.MESH.00863692	ETH.MESH.00863694
5/29/2003	Study spreadsheet	ETH.MESH.00863841	ETH.MESH.00863842
7/18/2003	Email Brian Luscombe to Dan Smith et al. re Design Validation	ETH.MESH.00864085	ETH.MESH.00864087
7/24/2003	Smith D email chain re TOVT developments	ETH.MESH.00864101	ETH.MESH.00864102
8/15/2001	Luscombe B email chain re Aug 11 program	ETH.MESH.00864131	ETH.MESH.00864133
5/21/2004	Robinson email re TVT-O	ETH.MESH.00864413	ETH.MESH.00864413
9/16/2004	Campbell, S email chain re Ongoing TVT-O Action Items	ETH.MESH.00864503	ETH.MESH.00864507
7/17/2003	Arnaud email re Mulberry IFU	ETH.MESH.00865147	ETH.MESH.00865147
3/2/2004	Owens C email chain re Reminder on BLUE mesh	ETH.MESH.00865322	ETH.MESH.00865323
3/1/2004	Burns email chain re Mulberry IFU	ETH.MESH.00866317	ETH.MESH.00866318

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6/29/2006	Meier email re Minutes Hamburg Meeting June 2nd	ETH.MESH.00870465	ETH.MESH.00870476
6/2/2006	Expert Meeting Minutes - Meshes for Pelvic Floor Repair	ETH.MESH.00870466	ETH.MESH.00870476
8/13/2006	London Brown, A email chainre LIGHTning clinical strategy	ETH.MESH.00870481	ETH.MESH.00870482
	Email from Carolyn Brennan (Project Manager, Worldwide Customer Quality) re Updated TVT and TVT-O Complication Rates 11-15-05	ETH.MESH.00875647	ETH.MESH.00875649
4/13/2005	Barbara McCabe email re Sheath Sales Tool	ETH.MESH.00994917	ETH.MESH.00994918
	Presentation: SUI, A Primary Care Perspective	ETH.MESH.00995657	ETH.MESH.00995657
	Complaint Reporting Statement	ETH.MESH.00995835	ETH.MESH.00995836
7/12/2011	Scion SBT Presentation - slide 9 - Abbrevio COGS, ASP, GP...	ETH.MESH.00996929	ETH.MESH.00996929
	Weisberg M Final Draft CER	ETH.MESH.00998286	ETH.MESH.00998291
	St. Hilaire email chain re Clinical Expert Report Laser Cut Mesh	ETH.MESH.00998292	ETH.MESH.00998293
6/22/2006	Gadot, Harel email re LCM - Launch Strategy EMEA	ETH.MESH.00998347	ETH.MESH.00998347
4/18/2006	Weisberg M and Robinson D CER	ETH.MESH.00998349	ETH.MESH.00998355
	TVT and TVT-O RMR Rev 1	ETH.MESH.01066916	ETH.MESH.01066932
	Spreadsheet DFMEA's TVT Classic	ETH.MESH.01068862	ETH.MESH.01068862
3/17/2009	Ciarrocca S email re Updated Mini TVT-O Deck	ETH.MESH.01147115	ETH.MESH.01147115
3/19/2009	Mini TVT-O Stage Gate: SBT Discovery Initiation	ETH.MESH.01147116	ETH.MESH.01147116
6/8/2009	Gynecare TVT Family of Products Tension-free Support for Incontinence Creative Brief Template	ETH.MESH.01184277	ETH.MESH.01184277
	Marketing Brochure - Make Data and Safety Your Choice	ETH.MESH.01186068	ETH.MESH.01186072
	Hinoul - IUGA From presentation to publication: ensuring quality in the reporting of urogynaecology research	ETH.MESH.01186613	ETH.MESH.01186613
	New Structures to create for GYNECARE TVT ABBREVO™ Anatomy Modules	ETH.MESH.01188589	ETH.MESH.01188613
4/4/2011	DRAFT - PA Strategy Review presentation	ETH.MESH.01201047	ETH.MESH.01201068
3/19/2010	Bryan L email chain re EBM Sub-team meetings for EWHU	ETH.MESH.01201387	ETH.MESH.01201389
8/8/2010	Page K email re Prof Ed deck (draft 2 still) w/o video	ETH.MESH.01201955	ETH.MESH.01201956
	Abbrevio Professional Education Presentation	ETH.MESH.01201957	ETH.MESH.01201957
1/7/2009	Kirkemo A email chain re My revised writeup of the DeLeval and Waltregny Visit	ETH.MESH.01202101	ETH.MESH.01202103
	Hinoul presentation: The future of surgical meshes: the industry's perspective	ETH.MESH.01203957	ETH.MESH.01203957
	TVT-Abbrevio RMR Rev 1	ETH.MESH.01212090	ETH.MESH.01212099

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4/25/2011	Briceno J email re 1st Post PRA review TVT Abbrevio	ETH.MESH.01216122	ETH.MESH.01216122
4/25/2011	Briceño J Memo re TVT Abbrevio - Risk Assessment Review	ETH.MESH.01216123	ETH.MESH.01216124
2/23/2011	Internal Notes - Memo	ETH.MESH.01216125	ETH.MESH.01216150
3/23/2010	Smith email chain re information regarding Scion	ETH.MESH.01216820	ETH.MESH.01216822
3/23/2010	Dormier E email chain re Meeting with Bridget - Transformation nature of Scion delivery system	ETH.MESH.01216831	ETH.MESH.01216833
	Memo by Lynn Hall re Summary of Findings and Next Steps from 10.12.01 TVT DTC Focus Groups	ETH.MESH.01217285	ETH.MESH.01217288
12/6/2004	Development Contract TVT-Next (TVTx)	ETH.MESH.01217673	ETH.MESH.01217690
	Revision History for dFMEA0000242	ETH.MESH.01218019	ETH.MESH.01218019
	TVT Laser Cut Mesh Rev 1	ETH.MESH.01218099	ETH.MESH.01218103
4/5/2007	Spychaj K memo re Shrinking meshes	ETH.MESH.01218361	ETH.MESH.01218367
1/20/2006	London Brown email chain re TVT U Completion Report Version 3	ETH.MESH.01218594	ETH.MESH.01218596
5/9/2006	Flatow J email chair re Particle loss on TVT	ETH.MESH.01219629	ETH.MESH.01219630
3/20/2006	Flatow Completion Report for Design Verification of TVT Laser Cut Mesh	ETH.MESH.01219984	ETH.MESH.01219994
8/14/2003	Kammerer G email chain re Aug 11 program	ETH.MESH.01220661	ETH.MESH.01220663
8/18/2003	Kammerer email chain re TVT Mesh Fraying	ETH.MESH.01220693	ETH.MESH.01220697
5/4/2006	Kammerer G email re New Standards for Urethral Slings	ETH.MESH.01221024	ETH.MESH.01221025
	An independent biomechanical evaluation of commercially available suburethral slings Article	ETH.MESH.01221055	ETH.MESH.01221058
3/9/2006	Kammerer G email chain re Elongation properties of LCM	ETH.MESH.01221618	ETH.MESH.01221619
3/7/2006	Weisberg, Robinson Clinical Expert Report	ETH.MESH.01221735	ETH.MESH.01221740
3/6/2006	Kammerer memo re Elongation Characteristics of Laser Cut PROLENE Mesh for TVT	ETH.MESH.01222075	ETH.MESH.01222079
	Ultrasonic Slitting of Prolene Mesh for TVT Feasibility Study	ETH.MESH.01222584	ETH.MESH.01222587
2/28/2003	Cirelli - Histological evaluation and Comparison of Mechanical Pull Out Strength of Prolene Mesh and Prolene Soft Mesh in a Rabbit Model	ETH.MESH.01222617	ETH.MESH.01222654
12/6/2010	Kirkemo A Dear Dr. unsolicited request for information letter	ETH.MESH.01226442	ETH.MESH.01226445
	Dr. Letter	ETH.MESH.01226446	ETH.MESH.01226449
4/22/2009	Email Piet Hinoul to Dan Smith re Meeting Minutes Prof deLeval 20/04/09	ETH.MESH.01238538	ETH.MESH.01238541

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4/22/2009	Email Piet Hinoul to Katrin Elbert et al. re Meeting Minutes Prof deLeval 20/04/09	ETH.MESH.01238551	ETH.MESH.01238551
4/20/2009	Piet Hinoul letter re meeting with Prof deLeval and Prof Waltregny	ETH.MESH.01238552	ETH.MESH.01238553
7/16/2009	Robinson D email chain re TVT RR IFU Version 5 071409_T-3466	ETH.MESH.01239065	ETH.MESH.01239066
	Spreadsheet DFMEA's TVT Classic	ETH.MESH.01247379	ETH.MESH.01247379
	Spreadsheet DFMEA's TVT Classic	ETH.MESH.01250926	ETH.MESH.01250926
	Spreadsheet DFMEA's TVT Classic	ETH.MESH.01250962	ETH.MESH.01250962
5/14/2010	Kirkemo A email chain re Review of Scion 2 year data	ETH.MESH.01252509	ETH.MESH.01252512
6/28/2002	Lawler T email re Polypropylene Mesh	ETH.MESH.01264260	ETH.MESH.01264260
	RMR TVT and TVT-O Rev 1	ETH.MESH.01265223	ETH.MESH.01265239
12/6/2010	Kirkemo A email re Your unsolicited request for medical information - MIR	ETH.MESH.01265511	ETH.MESH.01265511
	RMR for TVT and TVT-O Revision History for RMR-0000044	ETH.MESH.01268264	ETH.MESH.01268277
3/3/2008	Gadot H email re Next step in SUI sling	ETH.MESH.01279975	ETH.MESH.01279976
	TVT Laser Cut RMR Rev 2	ETH.MESH.01310061	ETH.MESH.01310065
	TVT RMR Rev 3	ETH.MESH.01310476	ETH.MESH.01310481
	Spreadsheet DFMEA's TVT Classic	ETH.MESH.01310482	ETH.MESH.01310482
5/14/2001	Target Sheet Design History: DH0263-DH0278	ETH.MESH.01317508	ETH.MESH.01317613
4/25/2002	DDSA Re-Evaluation for TVT	ETH.MESH.01317510	ETH.MESH.01317514
7/12/2000	TVT-2 needles Introducer Revision 8	ETH.MESH.01317515	ETH.MESH.01317524
5/14/2010	Biocompatibility Assessment of Medi-Line Use of Down Corning 200 Fluid (100 cst) In Gynecare TVT Products	ETH.MESH.01320395	ETH.MESH.01320519
7/7/2000	Incontinence/Pelvic Floor Management GYNECARE TVT Tension-free Support for Incontinence 2001 Marketing Plan	ETH.MESH.0137272	ETH.MESH.01137293
	Spreadsheet DFMEA's TVT Classic	ETH.MESH.01419741	ETH.MESH.01419741
3/25/2010	Gynecare TVT Abbrevio Launch Planning Stage Gate EWHU Board presentation	ETH.MESH.01538120	ETH.MESH.01538120
	Test Method Validation Protocol: Visual Acceptance criteria for seal of Blister PVA-112940-TMV-PR	ETH.MESH.01592467	ETH.MESH.01592490
	Test Method Validation Report: Visual Acceptance criteria for seal of Blister PVA-112940-TMV-RE Rev A	ETH.MESH.01592899	ETH.MESH.01592932
12/9/2008	Presentation: "Stop Coping. Start Living. Treatment Options for Urinary Incontinence."	ETH.MESH.01673341	ETH.MESH.01673341
	Spreadsheet re Faculty, Preceptors, Speaking Training, etc.	ETH.MESH.01674264	ETH.MESH.01674264
7/13/2010	Samuel S email re Key Steps Flashcare Clarification	ETH.MESH.01675805	ETH.MESH.01675806

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8/24/2010	Email from Carlos E. Lugo-Ponce to Darlene Jane Kyle et al re Product Complaint CC1007005-Taiwan	ETH.MESH.01745568	ETH.MESH.01745572
	Trzewik - Mesh design argumentation issues	ETH.MESH.01752532	ETH.MESH.01752535
	TVT-Secur Quality Board presentation	ETH.MESH.01758770	ETH.MESH.01758801
	Woods email chain re Trial	ETH.MESH.01760362	ETH.MESH.01760363
2/22/2008	Executive Summary - Preliminary results of peri-operative and 3-month outcomes from a world-wide observational registry of tension-free vaginal tapes in with with SUI	ETH.MESH.01775242	ETH.MESH.01775257
2/23/2007	Factors Related to Mesh Shrinkage: What do we know? A review of literature and internal studies	ETH.MESH.01782867	ETH.MESH.01782867
	Robinson email chain re TVT-S Cookbooks	ETH.MESH.01784428	ETH.MESH.01784435
3/7/2006	Clinical Expert Report for Laser Cut Mesh signed by Martin Weisberg, MD and David Robinson MD	ETH.MESH.01784823	ETH.MESH.01784828
1/17/2010	Hinoul, P email chain re +M relaxation	ETH.MESH.01785259	ETH.MESH.01785260
8/17/2010	Hinoul Clinical Expert Report	ETH.MESH.01795909	ETH.MESH.01795929
??/??/07	Gynecare TVT Secur Competitive Product Update	ETH.MESH.01805958	ETH.MESH.01805958
2/6/2010	Peebles R email re Mesh slides for NTM	ETH.MESH.01805963	ETH.MESH.01805963
2/5/2003	Tracey M email re Trip Report Format Mulberry 22Jan2003	ETH.MESH.01808310	ETH.MESH.01808310
1/31/2003	Tracey M Trip Report	ETH.MESH.01808311	ETH.MESH.01808318
	Leibowitz B Memo re Comparison of Laser-Cut and Machine-Cut TVT Mesh to Meshes from Competitive Devices (BE-2004-1641)	ETH.MESH.01809080	ETH.MESH.01809081
	London Brown Memo: VOC on new Laser Cut TVT Mesh	ETH.MESH.01809082	ETH.MESH.01809083
	London-Brown A Memto to Parisi, Mahar re VOC on new Laser Cut TVT Mesh	ETH.MESH.01809082	ETH.MESH.01809083
	Bell S email chain re VOC on Laser cut mesh	ETH.MESH.01811770	ETH.MESH.01811772
11/2/2004	Email from Patty Lancos to Manuel Castro and Dan Smith re FDA Prep	ETH.MESH.01813975	ETH.MESH.01813978
8/17/2004	Email from Dan Smith to Katrin Elbert re IFU changes	ETH.MESH.01814740	ETH.MESH.01814741
	VOC Summary Mini Me - Presentation	ETH.MESH.01816436	ETH.MESH.01816436
	VOC Summary Mini Me presentation	ETH.MESH.01816436	ETH.MESH.01816446
5/9/2006	Mesh development timeline	ETH.MESH.01816990	ETH.MESH.01816990
	Smith D email chain re TVT-Secur	ETH.MESH.01822361	ETH.MESH.01822363
3/30/2006	Email Mark Yale re TVT laser cut equivalency	ETH.MESH.01945854	ETH.MESH.01945854
2/16/2011	Biomechanical consideration for Pelvic floor mesh design	ETH.MESH.02010834	ETH.MESH.02010855
3/25/2010	Zaddem V email chain re Your input on 30 in 3 and Speed to launch	ETH.MESH.02013947	ETH.MESH.02013948

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2/23/2007	Ethicon Expert Meeting: Meshes for Pelvic Floor Repair brochure	ETH.MESH.02017152	ETH.MESH.02017158
7/15/2010	Email Vincenza Zaddem to Alyssa Kilayko re obt muscle thickness values	ETH.MESH.02019485	ETH.MESH.02019485
6/6/2005	Zaddem V email chain re MINT: 6/2/05 Materials Advisory meeting minutes	ETH.MESH.02020712	ETH.MESH.02020713
4/13/2005	Sunco C4001 Polypropylene Homopolymer MSDS	ETH.MESH.02026591	ETH.MESH.02026595
5/26/2011	Project NEO - DHF0000979 Medical Affairs NEO DRM Rationales	ETH.MESH.02030340	ETH.MESH.02030356
6/22/2001	Scientific Advisory Panel on Pelvic Floor Repair Preliminary Minutes	ETH.MESH.02089392	ETH.MESH.02089399
4/15/2008	Trip Notes	ETH.MESH.02090196	ETH.MESH.02090209
	Surgeon Evaluation Questions for Laser Cut Mesh	ETH.MESH.02106741	ETH.MESH.02106743
	Physician Post-Operative Questionnaire	ETH.MESH.02106803	ETH.MESH.02106803
	Division Meeting Notes: Continence Health	ETH.MESH.02108293	ETH.MESH.02108295
9/27/2007	Osman email chain re Wal-Mart Female Pelvic Health Poster Options	ETH.MESH.02114101	ETH.MESH.02114103
5/26/2009	Brennan email chain re TVT Complications Statement 2008	ETH.MESH.02122903	ETH.MESH.02122905
10/8/2008	Chaves email re MiniSling Abstract Overview & Nilsson Podcast	ETH.MESH.02123291	ETH.MESH.02123291
	Memo to Rippy re Mechanisms of Cytotoxicity for TVT Polypropylene Mesh	ETH.MESH.02134271	ETH.MESH.02134273
7/7/2010	Peter K email re TOPA timing - draft for review and input	ETH.MESH.02178872	ETH.MESH.02178873
6/24/2003	Toddywala R email re Project Mulberry	ETH.MESH.02180737	ETH.MESH.02180737
3/29/2004	de Leval J memo	ETH.MESH.02180759	ETH.MESH.02180761
	Menneret D email chain re Mesh Fraying: Dr. Eberhard letter	ETH.MESH.02180826	ETH.MESH.02180827
	Sibylle B Memo to Menneret D re TVT blue	ETH.MESH.02180828	ETH.MESH.02180830
	Translation of PD Doctor Eberhard's letter	ETH.MESH.02180833	ETH.MESH.02180833
	Completion Report, Design Verificaiton for Soft PROLENE Mesh/Mesh Curling	ETH.MESH.02182839	ETH.MESH.02182844
7/22/2004	Email Walji to Bogardus, et al. re ICS / Paris - Gala Invitee List	ETH.MESH.02201463	ETH.MESH.02201467
4/22/2011	TVTOPAC Cadaver Lab Report	ETH.MESH.02218436	ETH.MESH.02218439
	Presentation Script	ETH.MESH.02219162	ETH.MESH.02219164
2/23/2011	Material Specification for TVT Prolene Polypropylene Mesh Roll Stock, Rev. 5	ETH.MESH.02219202	ETH.MESH.02219210
	Design Verification Protocol for TVT-O PAC [TOPA Clinical] Project 14495, Version 1 Study Number AST-2010-0536	ETH.MESH.02221369	ETH.MESH.02221378

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	Stability Study Protocol: SS# 1617 Project TVT-O Partially Absorbable (PA) - To Support Clinical Build	ETH.MESH.02221379	ETH.MESH.02221388
5/29/2003	DHF 25 1-323 CE Mark of TVT - AA Kit.pdf	ETH.MESH.02222437	ETH.MESH.02222656
1/13/2011	TVT-O Marketing video	ETH.MESH.02229061	ETH.MESH.02229061
	The efficacy she needs with less mesh	ETH.MESH.02231537	ETH.MESH.02231538
2/13/2011	TVTA-083-11-2/13 - 1 Year RCT Trial Annotated Guide	ETH.MESH.02235375	ETH.MESH.02235387
4/12/2010	Extend the control of your hand 2010 TVTE-187-10-4/12 sales aid	ETH.MESH.02235661	ETH.MESH.02235664
	Patient Brochure - Stop coping. Start Living. Gynecare TVT Family of Products	ETH.MESH.02236580	ETH.MESH.02236595
??/??/10	Physician patient follow-up form letter	ETH.MESH.02236784	ETH.MESH.02236785
2/12/2010	2010 TVTS-029-10-2/12	ETH.MESH.02237103	ETH.MESH.02237104
	Spanish Gynecare TVT patient brochure	ETH.MESH.02237665	ETH.MESH.02237696
3/2/2011	Project TVTO PA SBT Stage Gate Chater Update Presentation	ETH.MESH.02238117	ETH.MESH.02238117
1/19/2005	Presentation: Mechanical vs. "Machine"-cut Mesh	ETH.MESH.02248778	ETH.MESH.02248778
	New Product Introduction Presentation	ETH.MESH.02249435	ETH.MESH.02249435
5/26/2009	All Active CAPA's	ETH.MESH.02250914	ETH.MESH.02250945
	Vellucci, L email chain re Ethicon sponsored study	ETH.MESH.02252005	ETH.MESH.02252007
7/13/2011	Email Bridget Ross (WW President, EWH&U) re FDA Health Notification	ETH.MESH.02253078	ETH.MESH.02253079
2/19/2010	Beath C email re clinical data	ETH.MESH.02254087	ETH.MESH.02254087
7/6/2010	Beath C email chain re 510K clearance	ETH.MESH.02254165	ETH.MESH.02254165
	Spreadsheet DFMEA's TVT Classic	ETH.MESH.02265802	ETH.MESH.02265802
	Spreadsheet DFMEA's TVT Classic	ETH.MESH.02265803	ETH.MESH.02265809
3/4/2008	Gadot H email chain re Next step in SUI Sling	ETH.MESH.02293673	ETH.MESH.02293677
	2009 Urology Advisory Board Meeting Somerville, NJ Agenda	ETH.MESH.02309289	ETH.MESH.02309290
	Pompilio S email re Information about FDA notification on use of mesh in pelvic surgery	ETH.MESH.02310653	ETH.MESH.02310657
2/7/2007	Robinson email chain re PLEASE DO NOT DISTRIBUTE THIE EMAIL!!! . . .broadcast bulletin re Dr. Levy	ETH.MESH.02316434	ETH.MESH.02316436
7/21/2009	Subramanian D email chain re EGS Mini TVTO	ETH.MESH.02322544	ETH.MESH.02322546
	TVT IFU through	ETH.MESH.02340306	ETH.MESH.02340369
??/??/09	P15506 Gynecare TVT IFU	ETH.MESH.02340402	ETH.MESH.02340470
2/11/2005	TVT IFU through	ETH.MESH.02340471	ETH.MESH.02340503
	TVT IFU through	ETH.MESH.02340504	ETH.MESH.02340567
1/7/2004	TVT-O IFU (1/7/2004-3/4/2005)	ETH.MESH.02340829	ETH.MESH.02340901
5/12/2010	TVT-O IFU (-present)	ETH.MESH.02340902	ETH.MESH.02340973
9/10/2010	TVT-ABBREVO IFU 20100910	ETH.MESH.02341203	ETH.MESH.02341267
	Prolene	ETH.MESH.02342102	ETH.MESH.02342102

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Date	Description	Bates - Begin	Bates - End
4/25/2013	IFU Index and Production Bates Range Chart	ETH.MESH.02342194	ETH.MESH.02342194
5/18/2011	PA Consulting Group Report: Investigating Mesh Erosion in Pelvic Floor Repair	ETH.MESH.02589032	ETH.MESH.02589079
3/9/2011	Kirkemo A email re Abbrevio - initial holding force - MIR	ETH.MESH.02592466	ETH.MESH.02592466
3/9/2011	Kirkemo A Dear Dr. unsolicited request for information letter	ETH.MESH.02592467	ETH.MESH.02592470
8/21/2009	Email David Waltregny to Piet Hinoul re TR: For Information - lot of TVT used for Deleval's tests	ETH.MESH.02596464	ETH.MESH.02596467
	TVT Abbrevio Dublin Meeting brochure	ETH.MESH.02596794	ETH.MESH.02596794
10/6/2010	Hinoul P email chain re Abbrevio use in Leige	ETH.MESH.02599695	ETH.MESH.02599695
	Hinoul P email chain re Dr. Waltregny contribution during Abbrevio training	ETH.MESH.02599885	ETH.MESH.02599886
5/14/2001	Design History CH1035 (bk2) - DH1036 (bk5)	ETH.MESH.02607272	ETH.MESH.02607814
1/28/2002	Corporate Product Characterization - Comparison of Particle Characteristics of Clear and 50% Blue PROLENE Mesh of TVT Device	ETH.MESH.02613804	ETH.MESH.02613805
	Ultrasonic Slitting of Prolene Mesh for TVT Feasibility Study - TOC	ETH.MESH.02614396	ETH.MESH.02614517
4/13/2005	Corporate Product Characterization Protocol to Evaluate Elongation, Particle Loss and Flexural Rigidity of TVT U PROLENE Mesh Laser-Cut vs Mechanical-Cut Version 1	ETH.MESH.02614599	ETH.MESH.02614603
	TVT - Freedom From Stress Urinary Incontinence	ETH.MESH.02619504	ETH.MESH.02619511
3/10/2004	TVT 20040310 What you Can do about it... TVT-Stress Urinary Incontinence in Women	ETH.MESH.02619601	ETH.MESH.02619616
	TVT Classic 1999-2000 Issue Report	ETH.MESH.02620354	ETH.MESH.02621558
	Issue Report TVT Retropubic 1999-2000 Open Date Between 01-Jan-1999 and 31-Dec-2000	ETH.MESH.02620681	ETH.MESH.02620685
	Issue Report TVT Retropubic 2001 Open Run Date Between 01-Jan-2001 and 31-Dec-2001	ETH.MESH.02621559	ETH.MESH.02622455
	Issue Report TVT Retropubic 2001 Open Date Between 01-Jan-2001 and 31-Dec-2001	ETH.MESH.02621946	ETH.MESH.02621950
	Issue Report TVT Retropubic 2001 Open Date Between 01-Jan-2001 and 31-Dec-2001	ETH.MESH.02621961	ETH.MESH.02621965
	TVT Classic 2002 Issue Report	ETH.MESH.02623743	ETH.MESH.02625054
	TVT Classic 2003 Issue Report	ETH.MESH.02625055	ETH.MESH.02626377
	TVT Retropubic 2003 Issue Report	ETH.MESH.02625060	ETH.MESH.02625064
	Issue Report TVT Retropubic 2003 Open Date Between 01-Jan-2003 and 31-Dec-2003	ETH.MESH.02625065	ETH.MESH.02625069
	Issue Report TVT Retropubic 2003 Open Date Between 01-Jan-2003 and 31-Dec-2003	ETH.MESH.02625419	ETH.MESH.02625423
	Issue Report TVT Retropubic 2003 Open Date Between 01-Jan-2003 and 31-Dec-2003	ETH.MESH.02626097	ETH.MESH.02626101
	TVT Classic 2005-2007 Issue Reports	ETH.MESH.02627331	ETH.MESH.02628697

Rosenzweig Mullins Supplemental Reliance List

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Date	Description	Bates - Begin	Bates - End
5/25/2005	TVT Retropubic Issue Report No. 30005181	ETH.MESH.02627466	ETH.MESH.02627466
	TVT Classic 2008-2009 Issue Reports	ETH.MESH.02628698	ETH.MESH.02630133
	TVT Classic 2010-2012 Issue Reports	ETH.MESH.02630134	ETH.MESH.02632004
3/7/2012	Issues Report Run Between and	ETH.MESH.02652179	ETH.MESH.02652317
	Issue Report TVT-O 2005 Open Date Between 01-Jan-2005 and 31-Dec-2005	ETH.MESH.02653001	ETH.MESH.02653005
	Issue Report TVT-O 2010 Open Date Between 01-Jan-2006 and 31-Dec-2006	ETH.MESH.02654027	ETH.MESH.02654034
	Issue Report TVT-O 2010 Open Date Between 01-Jan-2010 and 31-Dec-2010	ETH.MESH.02656825	ETH.MESH.02656834
	Clinical Registry Report - Protocol Number: 300-06-006	ETH.MESH.02877814	ETH.MESH.02881493
	Robinson email chain re Pelvic Floor/Mesh Strategy	ETH.MESH.03160750	ETH.MESH.03160752
4/12/2008	Gauld email chain re Follow-up on US visit	ETH.MESH.03162936	ETH.MESH.03162938
1/28/2009	Hinoul P email chain re TVT World AE Report	ETH.MESH.03208548	ETH.MESH.03208549
2/25/2009	Email Jason Hernandez re Quick Response Needed to Finalize TVT WORLD Recommendation for Board Meeting on Monday Mar 2nd	ETH.MESH.03208738	ETH.MESH.03208738
	Robinson D email chain re Organization of EWHU Workshops	ETH.MESH.03259032	ETH.MESH.03259035
4/24/2009	Email Judi Gauld to Colin Urquhart re green journal	ETH.MESH.03259439	ETH.MESH.03259440
6/14/2006	Email Marie-Ange Damotte to Sungyoon Rha, et al. re TVT Laser Cut First Human Use - surgeon preference questionnaire	ETH.MESH.03274663	ETH.MESH.03274670
8/12/2007	Project plan Prosima M project lightning	ETH.MESH.03294572	ETH.MESH.03294581
	Run on eg log.txt	ETH.MESH.03334244	ETH.MESH.03334244
5/1/2006	Kammerer G email chain re French Standard on TVT & Meshes (Comments required)	ETH.MESH.03358217	ETH.MESH.03358224
3/6/2006	Kammerer G Memo to Weisbert and Robinson re Elongation Characteristics of Laser Cut PROLENE Mesh for TVR	ETH.MESH.03358398	ETH.MESH.03358402
2/11/2011	Email Jennifer Haby to Sheelu Samuel re CR Aprvd: TVTA-088-11_TVT ABBREVO Prof Ed Slides Revised	ETH.MESH.03419391	ETH.MESH.03419391
08/??/10	Clinical Data Review Presented at ICS/IUGA Aug 2010	ETH.MESH.03422160	ETH.MESH.03422162
	TVT IFU to present	ETH.MESH.03427878	ETH.MESH.03427946
8/16/2010	Email Brian Flynn to Jonathan Fernandez re permission	ETH.MESH.03432766	ETH.MESH.03432766
7/13/1999	Product Pointer for TVT Tension-free Vaginal Tape	ETH.MESH.03456775	ETH.MESH.03456776
3/26/2008	Bonnie Blair - Find out how to stop uring leakage like Bonnie did	ETH.MESH.03458123	ETH.MESH.03458138

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Date	Description	Bates - Begin	Bates - End
8/14/2008	TVT Brochure "The Choice to End Stress Urinary Incontinence. Find out how to stop urine leakage like Bonnie did"	ETH.MESH.03459088	ETH.MESH.03459104
9/5/2008	FOR IMMEDIATE RELEASE: New Study Offers More Than a Decade of Evidence for Minimally-Invasive Surgery to Treat Female Incontinence	ETH.MESH.03459211	ETH.MESH.03459212
	Patient advertisement for TVT "One day you have urine leakage. The next day you don't. End of story."	ETH.MESH.03460640	ETH.MESH.03460640
6/10/2002	Email Mark Yale re Wang's rejections	ETH.MESH.03483690	ETH.MESH.03483693
	Draper S email re Initial Letter to Manufacturer MHRA Re. . .	ETH.MESH.03488556	ETH.MESH.03488564
7/5/2010	MD&D Complaint Form - Complaint ID CC1007005	ETH.MESH.03497846	ETH.MESH.03497847
8/17/2010	MD&D Resolution Form	ETH.MESH.03497878	ETH.MESH.03497878
3/10/2005	Berger L Itt Wallingford J re Unknown TVT Ref #3005146	ETH.MESH.03499528	ETH.MESH.03499529
6/30/2008	Lepley email chain re Urgent New complaint/request for information	ETH.MESH.03502981	ETH.MESH.0350298Y
	Physician form letter re RVRS1 - Gynecare TVT Secur System	ETH.MESH.03509755	ETH.MESH.03509755
1/8/2008	Flores email chain re New complaint acknowledgement/request for info 10100062684	ETH.MESH.03509909	ETH.MESH.03509910
	Holloway Itt Ethicon France re fraying	ETH.MESH.03535750	ETH.MESH.03535750
??/??/1999	1999 Gynecare Multigeneration Product Plan Pprtfp;op	ETH.MESH.03544344	ETH.MESH.03544352
09/??/04	Physician Segmentation Study for Gynecare TVT Final Presentation - Copernicus	ETH.MESH.03571983	ETH.MESH.03572098
3/1/2005	Email Charlotte Owens to Carol Holloway re Medical Review file #30005136	ETH.MESH.03574916	ETH.MESH.03574919
4/5/2005	Email Charlotte Owens to Carin Rassier re Complaint 30005255	ETH.MESH.03575061	ETH.MESH.03575061
11/5/2004	MedWatch Report	ETH.MESH.03589219	ETH.MESH.03589220
9/1/2005	Consulting Agreement B-1 between Brian J. Flynn and Ethicon	ETH.MESH.03605398	ETH.MESH.03605402
	Consulting Agreement between Dr. Brian Flynn and Ethicon	ETH.MESH.03605457	ETH.MESH.03605463
3/19/2008	Email Kyung Yu to Susie Chilcoat re Flynn preceptorships	ETH.MESH.03614158	ETH.MESH.03614158
9/28/2009	Master Consulting Agreement between Brian J. Flynn and Ethicon	ETH.MESH.03618587	ETH.MESH.03618596
9/23/2004	"Professional Education for GYNECARE TVT Physician Training" updated draft by Marianne Kaminski	ETH.MESH.03624321	ETH.MESH.03624322
2/17/2015	List of Preceptor Names and Events Attended	ETH.MESH.03625982	ETH.MESH.03625982

Date	Description	Bates - Begin	Bates - End
4/19/2010	Wess A email chain re de leval paper	ETH.MESH.03627114	ETH.MESH.03627114
6/14/2010	2011 EWHU Business Planning presentation	ETH.MESH.03642659	ETH.MESH.03642659
01/??/10	Ethicon Women's Health and Urology Brand Equity Study Final Report	ETH.MESH.03643186	ETH.MESH.03643186
5/16/2011	US EWHU Executive Performance Review Presentation	ETH.MESH.03643726	ETH.MESH.03643726
2/16/2012	PowerPoint - EWHU Incontinence 2012 Pipeline Refresh	ETH.MESH.03644217	ETH.MESH.03644217
	Revision Hx FM-0000167 Revision 4	ETH.MESH.03652924	ETH.MESH.03652955
8/30/2010	Wise E email chain re DoC for TVT Abbrevio	ETH.MESH.03654499	ETH.MESH.03654499
	510(k) Premarket Notification GYNECARE TVTO-PA Continence System	ETH.MESH.03654649	ETH.MESH.03654701
7/30/2009	Email Takahito Hino to Patrice Napoda re TVT Japanese Package Insert	ETH.MESH.03656697	ETH.MESH.03656699
1/11/1998	Presentation: Biocompatibility of ULTRAPRO by Joerg L. Holste, DVM	ETH.MESH.03658577	ETH.MESH.03658577
7/3/1999	Chen Consulting, Inc., Products and Technologies for Incontinence and Pelvic Floor Defects, Focus on Biological Materials, Appendix I	ETH.MESH.03662660	ETH.MESH.03662693
7/3/1999	Chen Consulting, Inc., Products and Technologies for Incontinence and Pelvic Floor Defects, Focus on Biological Materials	ETH.MESH.03662694	ETH.MESH.03662719
6/23/1999	Chen Consulting, Inc., Products & Technologies for Incontinence and Pelvic Floor Defects Focus on Biological Materials - presentation	ETH.MESH.03662734	ETH.MESH.03662793
	MS455-012; Revision 18 Material Specification for Pelletized Unpigmented	ETH.MESH.03671138	ETH.MESH.03671147
1/6/2013	Amin D Gynecare Protfolio Presentation	ETH.MESH.03685918	ETH.MESH.03685925
	Email Martin Weisberg to Barbara McCabe re leVal	ETH.MESH.03715571	ETH.MESH.03715574
8/25/2003	Email Martin Weisberg to Dan Smith, et al. re Mulberry Final Draft #1	ETH.MESH.03715869	ETH.MESH.03715876
7/9/2003	Email Martin Weisberg to Terry Courtney re TVT question	ETH.MESH.03715978	ETH.MESH.03715980
9/13/2010	Meier CER Mesh Erosions	ETH.MESH.03721328	ETH.MESH.03721449
9/17/2009	Email Paul DeCosta to Thomas Divilio, et al. re: Mesh + Anti-proliferative agent	ETH.MESH.03722384	ETH.MESH.03722386
	Check Liste D'Inspection Qualite - Final TVT-TVT-AA	ETH.MESH.03730703	ETH.MESH.03730722
6/7/2002	Emails Richard Isenberg to Dr Wang re concerns for patient safety	ETH.MESH.03735432	ETH.MESH.03735433
7/18/2002	Isenbert R Note to File re TVT associated Obturator Nerve Syndrome Complaint	ETH.MESH.03736538	ETH.MESH.03736539
8/28/2000	Memo Marty Weisberg to Rick Isenberg re discussion with redacted	ETH.MESH.03736578	ETH.MESH.03736578

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Date	Description	Bates - Begin	Bates - End
11/1/2000	Memo Marty Weisberg to Rick Isenberg re Complaint	ETH.MESH.03736932	ETH.MESH.03736932
8/26/2005	TVT Obturator Complaint Note to File	ETH.MESH.03736967	ETH.MESH.03736968
	Emails Martin Weisberg and Dr Peggy Norton re TVT	ETH.MESH.03738466	ETH.MESH.03738467
9/6/2003	Email Martin Weisberg to Marianne Kaminski re TVT Response for Peggy Norton MD	ETH.MESH.03738468	ETH.MESH.03738470
5/18/2011	Berman, Robinson, Wang, Rhodes - Report - Investigating Mesh Erosion in Pelvic Floor Repair	ETH.MESH.03750903	ETH.MESH.03750950
	Table comparing meshes	ETH.MESH.03751168	ETH.MESH.03751168
5/18/2010	TVT Abbrevio Launch Planning Stage Gate PLT brochure	ETH.MESH.03753682	ETH.MESH.03753682
1/4/2010	Monthly Closed CAPA	ETH.MESH.03832685	ETH.MESH.03832692
3/7/2011	Garbarino S email chain re 2011 VOTE Team Conf Call - VOTE Team Questions	ETH.MESH.03898831	ETH.MESH.03898834
8/23/2005	Draft Clinical Expert Report Gynecare TVT Secur System by Martin Weisberg, Senior Medical Director	ETH.MESH.03905059	ETH.MESH.03905072
6/6/2001	Weisberg, M email chain re TVT recommendation from Dr. Alex Wang	ETH.MESH.03905472	ETH.MESH.03905477
	Gynecare Pro-lift Ad "Get the Facts, Be Informed, Make YOUR Best Decision"	ETH.MESH.03905968	ETH.MESH.03905975
	Graft or No Graft - Arnaud presentation	ETH.MESH.03906527	ETH.MESH.03906527
	Arnaud Memo "Confidential Trans-Obturator TVT-Procedure In-Out"	ETH.MESH.03907327	ETH.MESH.03907330
5/1/2002	"Second Generation TVT" by Axel Arnaud	ETH.MESH.03907468	ETH.MESH.03907469
6/6/2003	LeTreguilly L email chain re TVT Serious complication	ETH.MESH.03907853	ETH.MESH.03907854
1/19/2006	Van Dijk email chain re Ti-mesh research	ETH.MESH.03908029	ETH.MESH.03908031
8/21/2000	ARnaud A email chain re Pelvic floor repair Procedural Strategy	ETH.MESH.03909708	ETH.MESH.03909713
10/1/2001	New Products Development Gynecare Products by Axel Arnaud	ETH.MESH.03909721	ETH.MESH.03909733
	Emails Axel Arnaud to Martin Weisberg re Soft Prolene	ETH.MESH.03910175	ETH.MESH.03910177
	Arnaud email chain re Soft Prolene	ETH.MESH.03910183	ETH.MESH.03910185
10/4/2002	Report: Visit to Pr Jean de Leval	ETH.MESH.03910208	ETH.MESH.03910210
	Arnaud A email chain re Mini TVT - mesh adjustment	ETH.MESH.03910418	ETH.MESH.03910421
7/21/2004	Arnaud A email chain re TVT Erosion	ETH.MESH.03910799	ETH.MESH.03910800
2/20/2003	Arnaud A email chain re TVT complications (an Prof. Häusler)	ETH.MESH.03911107	ETH.MESH.03911108
1/31/2006	Arnaud A email chain re TVT - TVT-O Specifications	ETH.MESH.03911712	ETH.MESH.03911715

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Date	Description	Bates - Begin	Bates - End
6/1/2007	CDMA Eurpoe Meeting Urinary Incontinence Platform minutes June 1, 2007	ETH.MESH.03913651	ETH.MESH.03913665
5/5/2008	Arnaud email chain re sling business for SUI	ETH.MESH.03914629	ETH.MESH.03914630
5/2/2008	Arnaud email re Mini TVT-O timeline	ETH.MESH.03914631	ETH.MESH.03914631
5/2/2008	Arnaud A email re clinical trial timeline - Mini TVT-O	ETH.MESH.03914631E	ETH.MESH.03914631E
9/25/2008	Arnaud A email re TVT World registry	ETH.MESH.03914909	ETH.MESH.03914909
2/13/2001	Email Axel Arnaud to Dr Uwe re Dr Lucente/TVT Procedure Improvements/Prevention of Overstretching	ETH.MESH.03915380	ETH.MESH.03915380
4/14/2005	Toddywala, R email chain re Ultrapro	ETH.MESH.03915567	ETH.MESH.03915572
4/12/2005	Kammerer, G email chain re Ultrapro	ETH.MESH.03915588	ETH.MESH.03915590
4/23/2008	Hernandez email chain re Liege Trip Notes. doc	ETH.MESH.03916715	ETH.MESH.03916715
4/15/2008	Notes	ETH.MESH.03916716	ETH.MESH.03916727
1/7/2009	Hinoul P email chain re My revised writeup of the DeLeval and Waltregny visit	ETH.MESH.03916905	ETH.MESH.03916913
1/7/2009	Hinoul email chain re My revised writeup of the DeLeval and Waltregny visit	ETH.MESH.03916905	ETH.MESH.03916913
4/22/2009	Email Piet Hinoul to Katrin Elbert et al. re Meeting Minutes Prof deLeval 20/04/09	ETH.MESH.03917298	ETH.MESH.03917300
	Bianchi R email chain re TVT event	ETH.MESH.03917309	ETH.MESH.03917312
	Weisberg, M email re Mini TVT - mesh adjustment	ETH.MESH.03917375	ETH.MESH.03917378
	Univ De Leige, Centre Hospitalier Universitaire De Liege and Ethicon Licensing Agreement	ETH.MESH.03918253	ETH.MESH.03918264
	Marketing Plan TOVT	ETH.MESH.03918352	ETH.MESH.03918352
5/15/2003	Emails Brian Luscombe to Axel Arnaud et al. re: De Leval Publication	ETH.MESH.03918552	ETH.MESH.03918553
7/21/2003	Ciarrocca email chain re Gynemesh holding force in tissue	ETH.MESH.03919143	ETH.MESH.03919144
2/25/2010	Robinson D email chain re Concerns raised re TVT Abbrevio surgical procedure	ETH.MESH.03923426	ETH.MESH.03923430
	2.0 Products in Development	ETH.MESH.03924530	ETH.MESH.03924539
9/8/2003	Arnaud A email chain re TVT complication	ETH.MESH.03928696	ETH.MESH.03928697
2/20/2006	Arnaud email chain re TVM discussions	ETH.MESH.03929173	ETH.MESH.03929177
	History of TVT-O	ETH.MESH.03932909	ETH.MESH.03932911
	The history of TVT	ETH.MESH.03932912	ETH.MESH.03932914
4/30/2003	TVOT Meeting report . . . de Leval, Ruel, Daoud	ETH.MESH.03934952	ETH.MESH.03934967
4/3/2012	deLeval J email re Alerte TVT Abbrevio	ETH.MESH.03941617	ETH.MESH.03941618
4/3/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.03941621	ETH.MESH.03941622
4/2/2012	DeLeval J email re Alerte TVT Abbrevio	ETH.MESH.03941623	ETH.MESH.03941623
	Presentation: "The Science of "What's Left Behind"... Evidence & Follow-Up of Mesh Use for SUI by Doug H. Grier, MD"	ETH.MESH.03965159	ETH.MESH.03965195
3/6/2009	Emails Scott Finley to Melissa Chaves re Fast Break Update	ETH.MESH.03966039	ETH.MESH.03966040

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Date	Description	Bates - Begin	Bates - End
2/14/2011	Roji A email re VOTE team 2010 1:1 calls	ETH.MESH.03981288	ETH.MESH.03981290
4/4/2012	Steele J email chain re Alerte TVT Abbrevio	ETH.MESH.03985932	ETH.MESH.03985934
??/??/11	Ozog, Yves Doctorial Thesis: Theoretical and Experimental Evaluation of Implant Materials Used in Pelvic Organ Prolapse Repair	ETH.MESH.04005863	ETH.MESH.04006038
3/1/2012	Batke B email chain re AGES Pelvic Floor Conference - Gala Dinner Invitation	ETH.MESH.04015102	ETH.MESH.04015104
4/13/2005	Holste, J email chain re Ultrapro	ETH.MESH.04020134	ETH.MESH.04020137
3/15/2012	Innovations in Mesh Development by Boris Batke	ETH.MESH.04037600	ETH.MESH.04037600
10/??/00	TVT Update Success & Complications - Bernard Jacquetin	ETH.MESH.04044797	ETH.MESH.04044800
6/18/2008	KOL Interview: Carl G. Nilsson	ETH.MESH.04048515	ETH.MESH.04048520
6/18/2008	Carl G. Nilsson KOL Interview	ETH.MESH.04048515	ETH.MESH.04048520
	Presentation: TVTO Data 2006 & 2007 Ethicon Women's Health & Urology, The Netherlands	ETH.MESH.04049320	ETH.MESH.04049320
1/23/2009	Hinoul memo re meeting with Prof DeLeval and Prof Waltregny	ETH.MESH.04050265	ETH.MESH.04050267
	Marketing & Launch Plan	ETH.MESH.04061003	ETH.MESH.04061048
3/17/2011	Wess A email chain re Incontinence PMT: 3/3 meeting notes	ETH.MESH.04062405	ETH.MESH.04062407
	Grier Presentation - The Science of "What's Left Behind" . . . Evidence & Follow-Up of Mesh Use for SUI	ETH.MESH.04077109	ETH.MESH.04077145
	Meeting Agenda "AE and complication of the Isings	ETH.MESH.04081189	ETH.MESH.04081190
	Chen, Medical Assessment - . . . 68 issues from Germany	ETH.MESH.04081871	ETH.MESH.04081872
	Study Notes, Meng Chen, PhD, Possible Complications for Surgeries to Correct Pelvic Organ Prolapse	ETH.MESH.04082973	ETH.MESH.04082974
	Email Meng Chen to Carolyn Brennan re TVTs and bladder perforation	ETH.MESH.04090122	ETH.MESH.04090122
	Email Meng Chen to Sergio Gadaleta, et al. re #10100080654 and TVT IFUs	ETH.MESH.04092868	ETH.MESH.04092869
1/29/2009	Chen M email re TVT IFUs on tape extrusion, exposure and erosion	ETH.MESH.04093125	ETH.MESH.04093125
1/29/2009	Emails Bryan List to Meng Chen et al. re TVT IFUs on tape extrusion, exposure and erosion	ETH.MESH.04094863	ETH.MESH.04094864
9/24/2008	Email Melissa Day to Meng Chen, et al. re #10100078150	ETH.MESH.04099233	ETH.MESH.04099234
10/5/2010	Brennan email chain re 10100124625 etc. - MEMO re TVT-O particles	ETH.MESH.04101014	ETH.MESH.04101015
9/1/2010	Email Shalot Armstrong to Carlos E Lugo-Ponce re Product Complaint CC1007005-Taiwan	ETH.MESH.04101817	ETH.MESH.04101822
	Particles in TVTO Blisters presentation	ETH.MESH.04101824	ETH.MESH.04101824

Rosenzweig Mullins Supplemental Reliance List

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Date	Description	Bates - Begin	Bates - End
3/2/2006	Email Dr. James Hart to David Robinson re tv t o training	ETH.MESH.04122262	ETH.MESH.04122264
11/1/2007	11.1.07 Internal Australian Meeting Re Secur	ETH.MESH.04126728	ETH.MESH.04126730
1/9/2008	Maree, A email chain re TGA Meeting	ETH.MESH.04127133	ETH.MESH.04127134
??/??/1999	Synthetic vs. Biologic product matrix	ETH.MESH.04178861	ETH.MESH.04178876
9/15/1999	Major Executive Committee Actions July 20, 1999 through September 15, 1999	ETH.MESH.04193990	ETH.MESH.04193993
3/20/2003	Strategic Plan Challenge	ETH.MESH.04205632	ETH.MESH.04205636
6/3/2009	Chaves email re Fast Break Promotion Update	ETH.MESH.04314739	ETH.MESH.04314740
	Check Liste D'Inspection Qualite	ETH.MESH.04321393	ETH.MESH.04321396
	Check Liste D'Inspection Qualite	ETH.MESH.04321397	ETH.MESH.04321400
	Check Liste D'Inspection Qualite	ETH.MESH.04321401	ETH.MESH.04321404
	Check Liste D'Inspection Qualite	ETH.MESH.04321405	ETH.MESH.04321408
	Check Liste D-Inspection Qualite	ETH.MESH.04321409	ETH.MESH.04321412
	Check Liste D'Inspection Qualite	ETH.MESH.04321413	ETH.MESH.04321417
	Check Liste D'Inspection Qualite	ETH.MESH.04321418	ETH.MESH.04321435
	Check Liste D'Inspection Qualite	ETH.MESH.04321436	ETH.MESH.04321453
	Check Liste D-Inspection Qualite	ETH.MESH.04321454	ETH.MESH.04321471
	Check Liste D'Inspection Qualite	ETH.MESH.04321472	ETH.MESH.04321487
	Check Liste D'Inspection Qualite	ETH.MESH.04321488	ETH.MESH.04321503
5/31/2006	Visual Acceptance Criteria for Blister Sealing; VSE0007, Revision: D	ETH.MESH.04321670	ETH.MESH.04321681
	Visual Acceptance Criteria for Blister Sealing; VSE0007, Revision: E	ETH.MESH.04321682	ETH.MESH.04321693
	Visual Acceptance Criteria for Blister Sealing; VSE0007, Revision: F	ETH.MESH.04321694	ETH.MESH.04321705
	Visual Acceptance Criteria for Blister Sealing; VSE0007, Revision: G	ETH.MESH.04321706	ETH.MESH.04321717
1/28/2002	Particle Release Characteristics of Clear and Blue TVT Mesh Corporate Product Characterization	ETH.MESH.04384185	ETH.MESH.04384188
12/2/2005	CER - Gynecare TVT Secur System	ETH.MESH.04385229	ETH.MESH.04385245
	File - TVT vs Colposuspension for GS1	ETH.MESH.04448285	ETH.MESH.04448323
2/1/2012	Postmarket Surveillance Plan: PS120095 GYNECARE TVT Secure System KO52401	ETH.MESH.04474763	ETH.MESH.04474770
7/9/2002	FDA Communication re 522 Prosima	ETH.MESH.04927339	ETH.MESH.04927340
9/25/2010	Hinoul Presentation - An anatomic comparison of the traditional TVT-O versus a modified TVT-O procedure	ETH.MESH.04933406	ETH.MESH.04933406
4/2/2012	Hinoul P email chain re Prof de Leval - TVT Abbrevio	ETH.MESH.04938298	ETH.MESH.04938299
	Holste presentation: Lightweight Mesh Developments	ETH.MESH.04941016	ETH.MESH.04941049
8/23/2005	Email Paula Evans to Sungyoon Rha et al. re TVT Laser Cut Value Proposition and Forecast	ETH.MESH.04985249	ETH.MESH.04985252
6/29/2010	Smith email re New TVT +M mesh	ETH.MESH.04987190	ETH.MESH.04987191

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Date	Description	Bates - Begin	Bates - End
	Commonly Asked Questions and Objections script	ETH.MESH.05119622	ETH.MESH.05119631
	Mesh vs Non-Mesh Pending PR/Regulatory Issues	ETH.MESH.05120364	ETH.MESH.05120365
7/26/2012	Email Piet Hinoul to Axel Arnaud re article "The perils of commercially driven surgical innovation"	ETH.MESH.05125293	ETH.MESH.05125297
3/14/2011	Email Alyson Wess to Georgia Long, et al. re Incontinence PMT: 3/3 meeting notes	ETH.MESH.05163323	ETH.MESH.05163325
	Email Linda Linton re TVT 11 Year E-blast Results (1st Round)	ETH.MESH.05183409	ETH.MESH.05183410
	Mesh vs Non-Mesh Pending PR/Regulatory Issues	ETH.MESH.05210364	ETH.MESH.05210365
	Division flowcharts	ETH.MESH.05217971	ETH.MESH.05217976
4/7/2006	TVT IFU through	ETH.MESH.05222673	ETH.MESH.05222705
7/1/2010	TVT Abbrevio 510(k) Clearance and Application	ETH.MESH.05224295	ETH.MESH.05224391
	TVT Patent Portfolio - Slater-Tomko presentation	ETH.MESH.05236223	ETH.MESH.05236255
	Trzewik memo re Mesh design argumentation issues	ETH.MESH.05237034	ETH.MESH.05237037
	LIGHTning Project Charter - Meier et al presentation	ETH.MESH.05237336	ETH.MESH.05237382
4/8/2009	Hinoul email chain re Tensile Properties of POP Mesh	ETH.MESH.05238373	ETH.MESH.05238374
4/9/2009	Jones, S email re Tensile Properties of POP Mesh	ETH.MESH.05238382	ETH.MESH.05238384
	Article on pp change in sheep model	ETH.MESH.05240144	ETH.MESH.05240144
3/10/2005	Next Generation Mesh Discussion	ETH.MESH.05245427	ETH.MESH.05245428
3/11/2011	Master Consulting Agreement between Brian J. Flynn and Ethicon	ETH.MESH.05276086	ETH.MESH.05276097
2/1/2011	Master Consulting Agreement between Dr. Douglas Grier and Ethicon	ETH.MESH.05276184	ETH.MESH.05276194
7/6/2011	Miller D email chain re Prolift professional education	ETH.MESH.05337217	ETH.MESH.05337220
7/6/2011	Luscombe B email chain re request from Miller re lecture material	ETH.MESH.05337225	ETH.MESH.05337228
6/16/2010	Hart email chain re Investigator-Initiated Studies Policy	ETH.MESH.05347751	ETH.MESH.05347769
	LIGHTning Project Charter Presentation	ETH.MESH.05352721	ETH.MESH.05352766
	MSE0181; Revision A Pilot Neuchatal Material Specification SCION Right and Left inserter assembly	ETH.MESH.05367673	ETH.MESH.05367679
	Selecting the Right Mesh - Professional Education presentation	ETH.MESH.05403236	ETH.MESH.05403236
3/16/2011	Volpe email chain re TVT+M for Peter	ETH.MESH.05403773	ETH.MESH.05403773

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6/20/2003	Leibowitz Tensile Properties, Morphology Test Report	ETH.MESH.05442881	ETH.MESH.05442883
	Applied Science & Technology Performance Evaluation Abstract Biaxial testing of two commonly used Ethicon meshes	ETH.MESH.05442973	ETH.MESH.05442975
3/13/2006	Holste J email chair re Mesh and Tissue Contraction in Animal	ETH.MESH.05446127	ETH.MESH.05446128
??/??/02	Hellhammer et al. Scientific Statement - Shrinking Meshes?	ETH.MESH.05446129	ETH.MESH.05446132
7/6/2007	Engle email chain re How inert is polypropylene?	ETH.MESH.05447475	ETH.MESH.05447476
7/6/2007	Engel D email chain re How inert is polypropylene?	ETH.MESH.05447475	ETH.MESH.05447476
7/6/2007	Barbolt email chain re How inert is polypropylene?	ETH.MESH.05447481	ETH.MESH.05447482
7/6/2007	Barbolt email chain re How inert is polypropylene	ETH.MESH.05447481	ETH.MESH.05447482
	Seven Year Data for Ten Year Prolene Study	ETH.MESH.05453719	ETH.MESH.05453727
8/1/2006	Jürgen email re Fotos cadeavar lab	ETH.MESH.05454207	ETH.MESH.05454207
8/16/2004	Email James McDivitt to Thomas Barbolt re Autoclaving PROLENE	ETH.MESH.05456117	ETH.MESH.05456118
4/13/2005	Barbolt, T email chain re Ultrapro	ETH.MESH.05469908	ETH.MESH.05469912
2/9/2007	Presentation: The (clinical) argument of lightweight mesh in abdominal surgery by Boris Batke	ETH.MESH.05475773	ETH.MESH.05475822
	The (clinical) argument of lightweight mesh in abdominal surgery Presentation	ETH.MESH.05479411	ETH.MESH.05479411
	Mesh porosity chart	ETH.MESH.05479535	ETH.MESH.05479535
03/??/11	ETHICON Polypropylene Mesh Technology- Batke presentation	ETH.MESH.05479717	ETH.MESH.05479717
06/??/02	Monthly Report WW Clinical Research Activities Gynecare	ETH.MESH.05490280	ETH.MESH.05490311
04/??/00	European Clinical R&D Monthly Report	ETH.MESH.05493782	ETH.MESH.05493810
6/6/2000	"Meshes in Pelvic Floor Repair - Findings from literature review and conversations/interviews with surgeons" prepared by Brigitte Hellhammer	ETH.MESH.05493965	ETH.MESH.05493999
6/1/2001	Hellhammer email chain re WG: TVT instructions for use	ETH.MESH.05494064	ETH.MESH.05494066
	Raw material specification - TVT Secur * System (semi finished good from Neuchatel, Switzerland	ETH.MESH.05500891	ETH.MESH.05500901
	Materials - defect spreadsheet	ETH.MESH.05514963	ETH.MESH.05514963
	Smith D email chain re TVT-S Cookbooks	ETH.MESH.05519476	ETH.MESH.05519481
4/17/2000	Gynecare TVT Tension-free Support for Incontinence	ETH.MESH.05529274	ETH.MESH.05529275

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Date	Description	Bates - Begin	Bates - End
	Hoepffner, H email re Problem Statements for TVT Brainstorming Meeting	ETH.MESH.05529653	ETH.MESH.05529653
11/1/2004	Smith D email re Update from Oct 27 cadaver lab	ETH.MESH.05548122	ETH.MESH.05548123
4/29/2005	Komamycky P email chain re Bio compatibility samples	ETH.MESH.05549696	ETH.MESH.05549700
1/27/2005	Smith email re TVT-U	ETH.MESH.05553782	ETH.MESH.05553782
	Emails Patricia Hojnoski and Martin Weisberg et al. re: Updated TVT and TVT-O Complication Rates 11-15-05	ETH.MESH.05560961	ETH.MESH.05560963
4/27/2012	Hinoul P email chain re slings at surgery center	ETH.MESH.05572526	ETH.MESH.05572528
4/7/2011	Ethicon 360 Gynecare TVT Abbrevio uses a refined obturator procedure so that you can use less mesh with confidence	ETH.MESH.05572669	ETH.MESH.05572669
2/10/2011	Beath email chain re Ethicon Mesh DVD - FDA Request Follow Up	ETH.MESH.05573254	ETH.MESH.05573254
6/30/2003	Presentation: Marketing Plan VOC by Boris Batke Project Edelweiss	ETH.MESH.05585033	ETH.MESH.05585053
7/9/2007	Wohlert S email chain re How inert is polypropylene?	ETH.MESH.05588123	ETH.MESH.05588126
7/9/2007	Wohlert email chain re How inert is polypropylene?	ETH.MESH.05588123	ETH.MESH.05588126
5/14/2012	Vellucci email re 522 Guidance Document Gynecare Prosima	ETH.MESH.05600730	ETH.MESH.05600731
5/29/2012	Background Information GYNECARE Pelvic Floor Repair Products and GYNECARE TVT Secure	ETH.MESH.05600916	ETH.MESH.05600923
2/15/2011	FDA Review of PFR and SUI Mesh Products - Changing Regulatory Environment and Potential Impact on Ethicon Pipeline - presentation	ETH.MESH.05604390	ETH.MESH.05604399
4/9/2010	NCR Summary Report NCR10-01914	ETH.MESH.05620358	ETH.MESH.05620362
6/16/2010	NCR Summary Report NCR10-02107	ETH.MESH.05620371	ETH.MESH.05620382
6/16/2010	NCR Summary Report NCR10-02199	ETH.MESH.05620383	ETH.MESH.05620388
	PVP OQ for Foil Pouches	ETH.MESH.05639356	ETH.MESH.05639361
	TVT STAF PD 99/20 -- Meeting of Nov. 17, 1999 Summary	ETH.MESH.05641096	ETH.MESH.05641098
	Pelvic Floor Repair -- Surgeon's Feed-back on Mesh Concept	ETH.MESH.05644163	ETH.MESH.05644171
07/??/09	BUC July 2009 I&pf platforms presentation	ETH.MESH.05764101	ETH.MESH.05764101
1/3/2005	2005 Variable Compensation Plan Sales Representative	ETH.MESH.05768705	ETH.MESH.05768712
12/9/2010	Henderson M email chain re Q4 Spend	ETH.MESH.05791132	ETH.MESH.05791133
1/29/2004	Gynecare TVT Introduction to cross train the Uterine	ETH.MESH.05793690	ETH.MESH.05793693

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10/??/03	Gynecare 7 Year Data Indicates Strong Continued Safety and Effectiveness for GYNECARE TVT Tension-free Support for Incontinence	ETH.MESH.05794787	ETH.MESH.05794788
8/27/2004	Email Marianne Kaminski to Amy Vie, et al. re 2004 budget - PE August adjustments	ETH.MESH.05795299	ETH.MESH.05795300
9/24/2004	Gyncecare Mega Course Uterine Health Urodynamics Incontinence and Pelvic Floor Repair and the OB/GYN Surgeon, Urogynecologist and Urologist	ETH.MESH.05795309	ETH.MESH.05795315
4/13/2005	Emails Marianne Kaminski to Paul Parisi, et al. re Q1 PE results REVISED	ETH.MESH.05795322	ETH.MESH.05795324
	Presentation: Gynecare TVT Abbrevio Continence System Professional Education by Dr. Babcock	ETH.MESH.05806931	ETH.MESH.05806931
6/14/2012	TVT-172-12-6/14 Patient Brochure - Stop Coping. START LIVING. WHAT YOU SHOULD KNOW ABOUT STRESS URINARY INCONTINENCE	ETH.MESH.05815791	ETH.MESH.05815802
5/13/2011	Email Laura Hutto to Brian Luscombe re Flynn	ETH.MESH.05822684	ETH.MESH.05822693
	Chronic Pain Prevention/future - Bioengineer's point of view Presentation	ETH.MESH.05916450	ETH.MESH.05916450
	Presentation: Solving the Device Design Puzzle	ETH.MESH.05918082	ETH.MESH.05918116
5/4/2004	Schiaparelli J email re Marlex Experience	ETH.MESH.05918776	ETH.MESH.05918776
7/20/2007	Chomiak M email re Defining light weight mesh	ETH.MESH.05920616	ETH.MESH.05920617
7/2/2002	Corrective/Preventive Action TVT Tape	ETH.MESH.05961197	ETH.MESH.05961203
7/2/2002	Corrective/Preventive Action TVT Tape	ETH.MESH.05961204	ETH.MESH.05961211
9/11/2002	Corrective/Preventive Action TVT Tape	ETH.MESH.05961212	ETH.MESH.05961234
1/9/2003	Corrective/Preventive Action TVT Tape	ETH.MESH.05961304	ETH.MESH.05961315
	Asset Purchase Agreement	ETH.MESH.05972834	ETH.MESH.05972866
	Consulting Agreement between Dr. Douglas Grier and Ethicon	ETH.MESH.05973195	ETH.MESH.05973200
3/12/2012	Hinoul P email chain re Patient complication in Wichita, KS	ETH.MESH.05998775	ETH.MESH.05998778
4/3/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998803	ETH.MESH.05998804
4/3/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998805	ETH.MESH.05998806
4/3/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998807	ETH.MESH.05998808
4/2/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998811	ETH.MESH.05998812
4/5/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998816	ETH.MESH.05998818
4/5/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998819	ETH.MESH.05998820
4/11/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998821	ETH.MESH.05998823
5/10/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998835	ETH.MESH.05998836
8/28/2006	ICM Project Presentation	ETH.MESH.06001408	ETH.MESH.06001408
3/7/2011	Benjamin email re FDA ltr re 510k	ETH.MESH.06015196	ETH.MESH.06015196
3/28/2011	Proposed contents for TVTOPA Pre-IDE Meeting with FDA	ETH.MESH.06015198	ETH.MESH.06015198

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Date	Description	Bates - Begin	Bates - End
9/1/2010	Briceño Memo to DHF0000978 - TOPA re Preliminary Risk Analysis for TVT-O PA	ETH.MESH.06015227	ETH.MESH.06015229
	Savidge email chain re Mesh and Biomechanical Data for TVTO-PA 510(k)	ETH.MESH.06015836	ETH.MESH.06015839
2/8/2011	Dang email chain re K103727 - please advise	ETH.MESH.06016054	ETH.MESH.06016055
4/2/2006	Mahar K email chain re Laser Cut Mesh Positioning	ETH.MESH.06040171	ETH.MESH.06040173
3/19/2009	Mahar email chain re Credo debrief	ETH.MESH.06040657	ETH.MESH.06040658
	TVT-444-10-11/12 Patient brochure - stop coping. start living. As yourself . . . Are you suffering from any of these syptoms?	ETH.MESH.06087471	ETH.MESH.06087472
12/9/2010	TVTR-566-10-11/12 Physician brochure - Gynecare TVT	ETH.MESH.06087513	ETH.MESH.06087514
1/16/2004	Smith D email re Dedications	ETH.MESH.06164409	ETH.MESH.06164410
2/22/2011	Voelker email chain re Approval of EMQD10: ECO354770	ETH.MESH.06165103	ETH.MESH.06165105
4/26/2011	Smith email re TVT+M mesh	ETH.MESH.06165243	ETH.MESH.06165243
	Spreadsheet	ETH.MESH.06171801	ETH.MESH.06171801
	Divilio memo	ETH.MESH.06195201	ETH.MESH.06195205
9/24/2007	EPC131 Revision A Neuchatel Prolift+M Product Specification	ETH.MESH.06214296	ETH.MESH.06214300
7/28/2009	Bobertz email chain re URGENT: Resin information request	ETH.MESH.06239100	ETH.MESH.06239108
??/??/10	R&D CO-OP Welcome Guide Spring 2010	ETH.MESH.06260647	ETH.MESH.06260671
8/26/2011	Karl J email chain re Braskem. . . A Little History	ETH.MESH.06261965	ETH.MESH.06261967
10/5/2007	Global Harms List Document for Review & Comment by Medical Affairs Personnel	ETH.MESH.06372356	ETH.MESH.06372363
2/25/2010	Magalhaes I email chain re Concerns raised re TVT Abbrevio surgical procedure	ETH.MESH.06378084	ETH.MESH.06378089
5/5/2005	Seppa K Memo re Performance Evaluation of TVT U Prolene Mesh: Mechanical Cut versus Laser Cut Study (LIMS#BE-2005-1920) Version 3	ETH.MESH.06696367	ETH.MESH.06696379
4/25/2006	Minute - Tactile appraisal of TVT LCM & LCM-MC both vs MCM	ETH.MESH.06696589	ETH.MESH.06696592
	Abbrevio COGS	ETH.MESH.06767981	ETH.MESH.06767981
5/26/2009	ASTM Designation: F 2097 - 08 Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products	ETH.MESH.06806078	ETH.MESH.06806092
5/26/2009	F 2097 - 08 Standard Guide for Packaging of Medical Products	ETH.MESH.06806078	ETH.MESH.06806092
3/24/2005	Hunsicker email chain re ICS Submission	ETH.MESH.06828907	ETH.MESH.06828909
5/26/2000	Biocompatibility Review	ETH.MESH.06852118	ETH.MESH.06852129
8/8/1997	Cytotoxicity Risk Assessment	ETH.MESH.06852120	ETH.MESH.06852129
11/1/2011	Smith Memo re Scion SIS development history summary; VOC, Human factors, Cadaver labs, Internal R&D	ETH.MESH.06857127	ETH.MESH.06857132

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	Dodd presentation: TVT: Insights into the Making of a Revolution	ETH.MESH.06859904	ETH.MESH.06859931
	Gynecare TVT-S Competitive Product Update	ETH.MESH.06861473	ETH.MESH.06861473
??/??/07	Basell Purell MSDS	ETH.MESH.06861946	ETH.MESH.06861946
	Kammerer email re Ultra sonic slit TVT	ETH.MESH.06866919	ETH.MESH.06866919
2/13/2003	Presentation - Ultrasonic Slitting of TVT Mesh Technical Review	ETH.MESH.06866920	ETH.MESH.06866920
	ETH.MESH.06866921 attachment	ETH.MESH.06866921	ETH.MESH.06866921
6/30/2010	Landgrebe email chain re matrix - Cohera	ETH.MESH.06869163	ETH.MESH.06869166
2/14/2003	Due Diligence Growth Opportunity Outline re Project Mulberry Next generation TVT	ETH.MESH.06873447	ETH.MESH.06873458
7/21/2003	Email Janice Burns to Dan Smith, et al. RE: Design Validation	ETH.MESH.06880021	ETH.MESH.06880023
10/2/2003	de Leval, J, "Novel Surgical Technique for the Treatment of Female Stress Urinary Incontinence: Transobturator Vaginal Tape Inside-Out"	ETH.MESH.06880472	ETH.MESH.06880478
8/17/2004	Burns J email chain re TVT-O	ETH.MESH.06881576	ETH.MESH.06881580
7/11/2003	Email Brian Luscombe to Steve Bell, et al. re Ulmsten opinion on Mulberry	ETH.MESH.06884249	ETH.MESH.06884250
8/18/2004	Mahar K email re Dr. Jensen Follow UP	ETH.MESH.06884516	ETH.MESH.06884517
9/16/2004	Campbell email chain re Ongoing TVT-O Action Items	ETH.MESH.06884728	ETH.MESH.06884732
2/19/2004	Smith D email re TVT-O recognition Submission	ETH.MESH.06892171	ETH.MESH.06892172
9/13/2010	Customer Requirements Specification (CRS) for Project TVT-O PA Revision History	ETH.MESH.06917699	ETH.MESH.06917704
	Presentation - Scion PP	ETH.MESH.06921531	ETH.MESH.06921531
7/12/2011	Scion SBT - Presentation	ETH.MESH.06921562	ETH.MESH.06921562
9/10/2010	TVTO-PA Clinical Strategy - Final Version	ETH.MESH.06923868	ETH.MESH.06923871
	Memo Evaluation of the Mesh Elongation, Function of Number of Wales	ETH.MESH.06926711	ETH.MESH.06926714
3/10/2010	Kirkemo A email chain re Scion PA commercial recommendations	ETH.MESH.06927231	ETH.MESH.06927235
3/19/2010	Smith D email re Information regarding Scion	ETH.MESH.06927248	ETH.MESH.06927249
3/4/2009	Technical Assessment Mini TVT-O	ETH.MESH.06928076	ETH.MESH.06928077
4/30/2009	Email Henri Decloux to Valerie Emperado re T-Con follow up	ETH.MESH.06928168	ETH.MESH.06928168
1/28/2009	Urquhart email re TVT World AE Report w/attachment	ETH.MESH.07181044	ETH.MESH.07181044
1/18/2011	PA Consulting Group Mesh Erosion Interview Memo	ETH.MESH.07192412	ETH.MESH.07192414
6/22/2011	Investigating Mesh erosion in Pelvic Floor Repair - Report Bernman, Robinson, Wang Rhodes - presentation	ETH.MESH.07192929	ETH.MESH.07192929
3/12/2012	Savidge, et al response to email from Huntington re 'Clave' publication	ETH.MESH.07205369	ETH.MESH.07205370

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Date	Description	Bates - Begin	Bates - End
	FDA Communication re PS120095 GYNECARE TVT Secur System	ETH.MESH.07218087	ETH.MESH.07218088
8/6/2010	Clinical Evaluation Report, Robinson, Gynecare TVT Obturator System Tension-free Support for Incontinence	ETH.MESH.07219684	ETH.MESH.07219723
3/1/2012	Vellucci, L email chain re Polypropylene Mesh	ETH.MESH.07226377	ETH.MESH.07226379
2/28/2012	Hinoul P email chain re CER Abbrevio CER	ETH.MESH.07226914	ETH.MESH.07226963
3/31/2011	Hinoul email chain re Workshop on Vaginal Tapes	ETH.MESH.07236294	ETH.MESH.07236295
5/13/2012	de Leval J email chain re Alerte TVT Abbrevio	ETH.MESH.07318311	ETH.MESH.07318313
10/5/2010	Smith email chain re Need help on Sample Size for Stability Dimensions	ETH.MESH.07356789	ETH.MESH.07356790
2/23/2009	Zipfel R email chain re Ultrapro mesh info	ETH.MESH.07383730	ETH.MESH.07383731
03/??/02	Worldwide Clinical Trials, Medical Affairs Gynecare - Monthly Report	ETH.MESH.07387082	ETH.MESH.07387103
6/29/2009	Email Michelle Hurley to Jackie Sauer re SBT Meeting	ETH.MESH.07402878	ETH.MESH.07402879
3/6/2012	Response to MHRA inquiry regarding inertness of polypropylene mesh	ETH.MESH.07455220	ETH.MESH.07455221
8/4/2011	Lin ltt FDA re K103727 Gynecare TVTO-PA Continence System - Request for Withdrawal of 510k	ETH.MESH.07455424	ETH.MESH.07455425
??/??/08	ANSI/AAMI/ISO 10993-7:2008	ETH.MESH.07474296	ETH.MESH.07474407
3/5/2012	Savidge email chain re TVT-O mesh weight	ETH.MESH.07502642	ETH.MESH.07502645
	Biocompatibility Risk Assessment: PROSIMA Pelvic Floor Repair System (Mint)	ETH.MESH.07506983	ETH.MESH.07506985
3/14/2012	Independent MD&D Sector Audit by QualityHub, Inc. Pore size	ETH.MESH.07724068	ETH.MESH.07724080
2/24/2012	Lapinskas, I, email chain originating re Discussion of 3.5 mil Prolene production	ETH.MESH.07730291	ETH.MESH.07730295
10/??/12	The efficacy she need with less mesh. Clinical Data Review - 3 Year Data	ETH.MESH.07808480	ETH.MESH.07808481
??/??/12	Frequently Asked Questions Clinical Data Review 3-Year Data Flashcard	ETH.MESH.07808484	ETH.MESH.07808486
9/17/1998	Lessig email re PROLENE Mesh Redesign Project	ETH.MESH.07877085	ETH.MESH.07877085
	Scion PA Commercial Strategy	ETH.MESH.07903520	ETH.MESH.07903520
6/30/2011	Affeld, T email chain re PS vs +M	ETH.MESH.07903682	ETH.MESH.07903683
1/18/2005	Hojnoski Personnel File	ETH.MESH.07931874	ETH.MESH.07931886
	FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of POP and SUI	ETH.MESH.07937826	ETH.MESH.07937828
2/21/2008	Vie email chain re TVTO vs. Boston Obtryx	ETH.MESH.07937979	ETH.MESH.07937981
2/21/2008	Vie email chain re TVTO vs Boston Obtryx	ETH.MESH.07937979	ETH.MESH.07937981
5/13/2011	Decker R email chain re Abbrevio letter	ETH.MESH.07954703	ETH.MESH.07954705

Rosenzweig Mullins Supplemental Reliance List

01/06/2017

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Date	Description	Bates - Begin	Bates - End
5/12/2011	Email Ronald Decker to Walter Boldish, et al. re Abbrevio letter	ETH.MESH.07954867	ETH.MESH.07954867
12/8/2004	TVT 20041208 Gynecare TVT Tension-free Support for Incontinence Patient Brochure reprint /Robin Osman	ETH.MESH.08003197	ETH.MESH.08003212
7/17/2006	TVT 20060717 Patient Brochure - Find out how to stop urine leakage like Bonnie did	ETH.MESH.08003215	ETH.MESH.08003230
9/27/2006	TVT016R6 Patient brochure - Find out how to stop urine leakage like Bonnie did	ETH.MESH.08003231	ETH.MESH.08003246
??/??/07	TVT 20070531 Patient Brochure - The Choice to End Stress Urinary Incontinence Find out how to stop urine leakage like Bonnie did	ETH.MESH.08003247	ETH.MESH.08003262
5/31/2007	Marketing Brochure - One day you have urine leakage. The next day you don't. End of Story.	ETH.MESH.08003263	ETH.MESH.08003278
	TVVT016R9 Patient brochure - stop coping. start living	ETH.MESH.08003279	ETH.MESH.08003294
2/7/2011	TVT-039-11-1/13 Patient brochure - stop coping. start living	ETH.MESH.08003295	ETH.MESH.08003302
1/26/2011	Patient Brochure - Treatment Options for Stress Urinary Incontinence -- stop coping. start living.	ETH.MESH.08003303	ETH.MESH.08003318
	Presentation TVT Abbrevio Incontinence System Professional Education by Dr. Grier	ETH.MESH.08004035	ETH.MESH.08004035
2/24/2011	Email Jonathan Fernandez to Brian Flynn, et al. re Flynn contracts	ETH.MESH.08005908	ETH.MESH.08005909
6/26/2009	Email Brian Flynn to Jonathan Fernandez re Contracted Pricing	ETH.MESH.08007248	ETH.MESH.08007249
	Grier Consulting Agreement Requisition Form	ETH.MESH.08007502	ETH.MESH.08007512
2/24/2010	Email Jonathan Fernandez to Carol Padgett re Dr. Alvina Driscoll	ETH.MESH.08014324	ETH.MESH.08014327
6/11/2010	Jones email chain re Prosima Preceptorships	ETH.MESH.08023341	ETH.MESH.08023342
12/9/2010	Irvin email re 12/8 Post Call Notes	ETH.MESH.08041930	ETH.MESH.08041931
	Hurricane and The Stars Divisional Meeting Orlando Marriott World Center Agenda	ETH.MESH.08050183	ETH.MESH.08050183
5/15/2012	Master Consulting Agreement between Melvyn A. Anhalt and Ethicon	ETH.MESH.08065931	ETH.MESH.08065943
5/1/2012	Pramudji fax re Contract	ETH.MESH.08066401	ETH.MESH.08066414
3/26/2013	Rahman communication - AUGS Issues Statement Opposing the Restriction of Surgical Options for Pelvic Floor Disorders	ETH.MESH.08073801	ETH.MESH.08073803
??/??/2011	TVT-US	ETH.MESH.08078799	ETH.MESH.08078799
9/11/2004	Gynecare University Program Las Vegas, Nevada	ETH.MESH.08107153	ETH.MESH.08107155
6/1/2005	Oldelehr email re gynecology vs urology	ETH.MESH.08107933	ETH.MESH.08107933

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Date	Description	Bates - Begin	Bates - End
6/15/2006	Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Materials for Medical Devices	ETH.MESH.08164248	ETH.MESH.08164256
7/28/1999	TVT Development Team Meeting Minutes	ETH.MESH.08165497	ETH.MESH.08165499
	Emails Dr. Brigitte Hellhammer to Dr. Hans-Jochen Hoepffner, et al. re Cardozo Trial	ETH.MESH.08167644	ETH.MESH.08167645
2/28/2011	Kevin Frost email chain re SGS Fellows Symposium	ETH.MESH.08170224	ETH.MESH.08170232
6/27/2013	Ex T-722 Mitchell - Clinical Expert Report Gynecare Prolift +M	ETH.MESH.08315779	ETH.MESH.08315810
	LCM Project: Photographs Comparing Laser Cut Mesh vs Mechanical Cut Mesh	ETH.MESH.08334245	ETH.MESH.08334245
9/30/2010	Email Kevin Mahar to Libby Lewis RE: Key docs at AUGS	ETH.MESH.08344659	ETH.MESH.08344659
	Mahar email chain re Contact at Lifescan who ran the BB King campaign	ETH.MESH.08345895	ETH.MESH.08345895
	TVT Obturator System Product Description	ETH.MESH.08376560	ETH.MESH.08376564
2/23/2013	Roseleip email chain re TVT Heads up	ETH.MESH.08422124	ETH.MESH.08422125
	Toglia Presentation - The Mesh Story working copy	ETH.MESH.08426862	ETH.MESH.08426867
	Cecchini TVT package insert comments	ETH.MESH.08505071	ETH.MESH.08505071
	Medhekar email chain re Ethicon Mesh DVD - FDA Request Follow-Up	ETH.MESH.08516130	ETH.MESH.08516132
11/9/2010	Krause email chain re Ethicon DVD	ETH.MESH.08516133	ETH.MESH.08516134
	Zaddem email re cannulae metal particles	ETH.MESH.08561511	ETH.MESH.08561511
	Kirkemo ltr to Dr. Kondrup re request for information	ETH.MESH.08570968	ETH.MESH.08570970
	Equivalence Supported by Pre-clinical Performance Studies	ETH.MESH.08581280	ETH.MESH.08581282
2/8/2010	Email Aaron Kirkemo to Alyson Wess RE: TVT Abbrevio and surgicenters	ETH.MESH.08581412	ETH.MESH.08581413
	Literature on TVT-O sling and pain management	ETH.MESH.08584142	ETH.MESH.08584143
??/??/10	The efficacy she needs with less mesh - TVT Abbrevio	ETH.MESH.08614017	ETH.MESH.08614021
	Franchise Procedure for Controlling Substances of Concern Revision History PR-0000558	ETH.MESH.08664680	ETH.MESH.08664686
2/8/2008	Master Consulting Agreement between Ethicon (signed by Price St. Hilaire) and Carl Nilsson	ETH.MESH.08692660	ETH.MESH.08692667
	Cancellation Agreement between Ethicon, Inc., Contape S.A., and the estate of Professor Ulf Ivar Ulmsten	ETH.MESH.08692670	ETH.MESH.08692672

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Date	Description	Bates - Begin	Bates - End
	Consulting Agreement between Ethicon, Inc. and Contape S.A. and Professor Ulf Ivar Ulmsten	ETH.MESH.08692673	ETH.MESH.08692696
2/8/2008	Nilsson Master Consulting Agreement	ETH.MESH.08692936	ETH.MESH.08692943
3/28/2002	Letter from Howard Zauberman (Ethicon) to Mr. Jan Johansson (Director, Eurosund Medical AB)	ETH.MESH.08695896	ETH.MESH.08695896
2/13/1997	Consulting & Technology Agreement between Johnson & Johnson International and Professor Ulf Ivar Ulmsten	ETH.MESH.08696050	ETH.MESH.08696055
2/26/1997	Medscan Agreement	ETH.MESH.08696084	ETH.MESH.08696134
	Medscand Agreement Files	ETH.MESH.08696085	ETH.MESH.08696134
	Instruction Standard TVT EXACT product Plan and Rationald Appendix I, Revision A	ETH.MESH.08776231	ETH.MESH.08776238
6/6/2011	CA to audit abbrevo(1)	ETH.MESH.08776497	ETH.MESH.08776521
	Nonnenmann Performance Evaluation - Memo re TVT+M Mesh Tensile Strength	ETH.MESH.08776793	ETH.MESH.08776794
	Risk Management Report TVT Laser Cut Mesh (LCM) Revision History for (RMR-000017) Revision 2	ETH.MESH.08792102	ETH.MESH.08792106
1/28/2005	Carino email chain re Recommendations for Non-Sales and Marketing Glamour Trip Award	ETH.MESH.08792936	ETH.MESH.08792938
	Cario email chain re Dr. Wang's proposal	ETH.MESH.08793207	ETH.MESH.08793210
4/25/2002	Email Ettore Carino to Kimberly Mullarkey re FW: DTC Review	ETH.MESH.08793552	ETH.MESH.08793553
01/??/02	DTC Advertising Patient Potential January 2002 Presentation	ETH.MESH.08793554	ETH.MESH.08793554
8/21/2000	Isenberb email re WOW Business Plan -- 2001, Clinical Research	ETH.MESH.08793646	ETH.MESH.08793647
8/18/2000	Study Justification: Gynecare Clinical Research Program 2001 spreadsheet	ETH.MESH.08793648	ETH.MESH.08793648
6/18/2001	2002-2003 US Marketing Plan for Gynecare TVT Tension-free Support for Incontinence	ETH.MESH.08798099	ETH.MESH.08798110
	Ailawadi - Does Material Matter - final	ETH.MESH.08968369	ETH.MESH.08968378
3/29/2011	Frost K email re PF Summit Presentations	ETH.MESH.08969368	ETH.MESH.08969368
7/29/2008	Kadadkia R email chain re TVT LCM - launch delay due to OQ failure	ETH.MESH.09004550	ETH.MESH.09004553
	Elongation test data	ETH.MESH.09004554	ETH.MESH.09004554
	Elongation test data - delayed launch	ETH.MESH.09004555	ETH.MESH.09004555
	Savidge S email chain re 510k Mint tests pending	ETH.MESH.09052531	ETH.MESH.09052534
9/21/2010	Paradise email chain re GYNecare TVT Obturator Sales: Feedback needed	ETH.MESH.09133724	ETH.MESH.09133725
2/1/2012	Grier Consulting Agreement Requisition Form	ETH.MESH.09155883	ETH.MESH.09155895
2/1/2012	Consulting Agreement Requisition Form - Part I Ethicon and Melvyn A. Anhalt	ETH.MESH.09155909	ETH.MESH.09155920

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Date	Description	Bates - Begin	Bates - End
6/16/2012	ARTISYN Advisory Board notes	ETH.MESH.09158424	ETH.MESH.09158430
	Destefano C email re CR Approved: TVTA-474-10-10_12 Gynecare TVT Abbrevio Clinical Data Review Flashcard	ETH.MESH.09161482	ETH.MESH.09161484
8/5/2010	Amin email chain re Gynecare TVT Abbrevio advisory board members	ETH.MESH.09164480	ETH.MESH.09164481
	Abbrevio marketing video script	ETH.MESH.09170211	ETH.MESH.09170213
5/18/2010	Gynecare TVT Abbrevio Launch Planning Stage Gate PLT	ETH.MESH.09183969	ETH.MESH.09184024
2/27/2010	Peebles email re participation next week - copy-approved slides	ETH.MESH.09214438	ETH.MESH.09214438
	Toglia, The Mesh Story presentation	ETH.MESH.09214439	ETH.MESH.09214439
9/30/2010	Peebles R email re Transcription	ETH.MESH.09218058	ETH.MESH.09218058
9/25/2010	Abbrevio Ad Board Notes	ETH.MESH.09218059	ETH.MESH.09218064
4/30/2012	Peebles, R email chain re Alerte TVT Abbrevio	ETH.MESH.09227438	ETH.MESH.09227439
4/3/2012	Peebles R email chain re Alerte TVT Abbrevio	ETH.MESH.09227440	ETH.MESH.09227441
1/28/2010	Flores email chain re Continence Health Brand Team - TVT Feedback	ETH.MESH.09234951	ETH.MESH.09234952
1/21/2010	TVT Matketing email re 2010 Planning -- "Voice of the Customer" feedback	ETH.MESH.09234953	ETH.MESH.09234954
2/16/2010	Toglia M email chain re Ethicon Women's Health and Urology National Training meeting - TVT	ETH.MESH.09235084	ETH.MESH.09235085
	Rousseau R Memo re Meeting Minutes of Project Planning Meeting	ETH.MESH.09264884	ETH.MESH.09264885
	Memo R. Rousseau to Project Team re Meeting Minutes of Project Planning Meeting	ETH.MESH.09264884	ETH.MESH.09264885
8/17/1998	Rousseau Memo to Lessig re Prolene Mesh Re-Design Project	ETH.MESH.09264945	ETH.MESH.09264946
9/23/1998	D Aversa email chain re Prolene Mesh Sheets Research	ETH.MESH.09266465	ETH.MESH.09266466
6/23/1998	Ellington L email re Prolene Mesh for TVT	ETH.MESH.09266657	ETH.MESH.09266658
6/17/1998	Tang email chain re Prolene Mesh Update	ETH.MESH.09266659	ETH.MESH.09266660
9/7/1998	Tang email chain re Mesh 3	ETH.MESH.09266668	ETH.MESH.09266671
11/4/2005	Rousseau, R email chain re Gynemesh PS w/Monocryl	ETH.MESH.09268506	ETH.MESH.09268508
1/4/2000	Dormier email chain re LcBlanc CME Live on Medscape	ETH.MESH.09273600	ETH.MESH.09273601
8/18/1999	Rousseau email re Samples of PROLENE Mesh	ETH.MESH.09275875	ETH.MESH.09275876
	Memo to Rousseau re Biocomp Risk Assess Prolene	ETH.MESH.09279161	ETH.MESH.09279161
	Notes re customers frustration with Ethicon rep	ETH.MESH.09293114	ETH.MESH.09293114
5/18/2010	GYNECARE TVT ABBREVO™ Launch Planning Stage Gate PLT - May 18, 2010 - presentation	ETH.MESH.09294125	ETH.MESH.09294125
9/28/2001	2002 US Marketing Plan for TVT	ETH.MESH.09306898	ETH.MESH.09306910
12/2/1999	Biocomp risk assessment GPS revised	ETH.MESH.09346417	ETH.MESH.09346418

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Date	Description	Bates - Begin	Bates - End
12/2/1999	Memo to R. Rousseau re Biocompatibility Risk Assessment for Soft PROLENE Mesh	ETH.MESH.09346419	ETH.MESH.09346420
8/7/2012	Chen email chain re New Complaint Form 23125	ETH.MESH.09478633	ETH.MESH.09478636
8/20/2012	Chen M email chain re Urgent - MDR serious injuries Gynecare France	ETH.MESH.09478684	ETH.MESH.09478688
8/27/2008	Brennan email chain re TVT-S Mesh Torn Complaint Review for Wednesday morning Conf Call	ETH.MESH.09504558	ETH.MESH.09504559
8/27/2008	Scavona email chain re PQI TVT S	ETH.MESH.09504568	ETH.MESH.09504571
4/13/2010	Trzewik J email chain re laser cutting	ETH.MESH.09656790	ETH.MESH.09656795
	Engel email chain re Gynemesh PS w/Monocryl	ETH.MESH.09664947	ETH.MESH.09664950
7/14/2006	Trzewik email re Netzdiskussion	ETH.MESH.09671612	ETH.MESH.09671612
	Material specification spreadsheet	ETH.MESH.09671620	ETH.MESH.09671620
6/19/2013	Issue Reports Open Date BEtween 01-Jan-2005 and 02-Jun-2013	ETH.MESH.09732998	ETH.MESH.09733718
??/??/13	TVT-131-13 Patient Brochure - stop coping start living. What You Should Not About Stress Urinary Incontinence	ETH.MESH.09744840	ETH.MESH.09744845
??/??/12	TVT-312-12 Patient Brochure - stop coping. start living. GYNECARE TVT Family of Products	ETH.MESH.09744848	ETH.MESH.09744855
	Stop Coping. Start Living. What you should know about stress urinary incontinence. Brochure	ETH.MESH.09744858	ETH.MESH.09744863
??/??/13	TVT Abbrevio information pamphlet	ETH.MESH.09744866	ETH.MESH.09744867
5/3/2013	TVT 20130503	ETH.MESH.09744870	ETH.MESH.09744871
11/1/1999	Ethicon Scientific Inf Svcs email chain re new Cook product	ETH.MESH.09745518	ETH.MESH.09745527
5/30/1985	Memo N.R. Cholvin to Dr. R.L. Kronenthal, et al. re Protocol for 10 Year In Vivo Study of Monofilament Sutures	ETH.MESH.09746373	ETH.MESH.09746448
9/6/2000	Ltt Nilsson from Zauberger re Surgeon Panel	ETH.MESH.09746615	ETH.MESH.09746617
9/16/1997	PAC Meeting Review - Tension Free Vaginal Tape (TVT) Ulmsten Device	ETH.MESH.09747632	ETH.MESH.09747643
10/1/1997	Linsky C email re Recommendation not to Accelerate TVT Program	ETH.MESH.09747724	ETH.MESH.09747725
9/11/1997	Linsky email re TVT (Ulmsten) -510k submission	ETH.MESH.09747728	ETH.MESH.09747728
	Barabas Memo re Operations Due Diligence - TVT/Tome	ETH.MESH.09748041	ETH.MESH.09748044
	Consultancy Agreement	ETH.MESH.09748842	ETH.MESH.09748846
	Consultancy Agreement	ETH.MESH.09748848	ETH.MESH.09748853
	Seven Year Data for Ten Year Prolene Study	ETH.MESH.09888187	ETH.MESH.09888223
	ABBREVO Lessons Learned Preliminary Report-out Presentation	ETH.MESH.09905181	ETH.MESH.09905181
	Survey Results	ETH.MESH.09905193	ETH.MESH.09905193

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Date	Description	Bates - Begin	Bates - End
	Abbrevio Lessons Learend - Summary Report out	ETH.MESH.09909020	ETH.MESH.09909025
4/15/2008	Trip Notes	ETH.MESH.09909642	ETH.MESH.09909655
5/8/2013	Biocompatibility Risk Assessment Report for Gynecare TVT Product Family	ETH.MESH.09909830	ETH.MESH.09909882
	Things to consider as we assess next steps for a next generation sling	ETH.MESH.09911296	ETH.MESH.09911299
	Smith memo re Things to consider as we assess next steps for a next generation sling	ETH.MESH.09911296	ETH.MESH.09911299
4/15/2010	Project Mini TVT-O Team: Gynecare TVT Abbrevio Continence System	ETH.MESH.09922406	ETH.MESH.09922406
	Elbert Memo to TVTO PA (TOPA) DHF0000978 re R&D Memorandum on PA Mesh Assessments for TVTO-PA	ETH.MESH.09922570	ETH.MESH.09922578
3/24/2010	Iacobone email chain re Stability Testing	ETH.MESH.09932848	ETH.MESH.09932849
09/??/10	Neuchatel - September 2010 Roles and Responsibilities	ETH.MESH.09932902	ETH.MESH.09932912
09/??/10	Neuchatel - September 2010 Roles and Responsibilities	ETH.MESH.09932908	ETH.MESH.09932918
5/18/2010	Gynecare TVT ABBREVO Launch Planning Stage Gate PLT May 18, 2010 Presentation	ETH.MESH.09936426	ETH.MESH.09936426
1/21/2011	Gynecare TVT Abbrevio RDLT 3 Month Post-Launch Close-out January 21, 2011 Presentation	ETH.MESH.09936503	ETH.MESH.09936503
3/6/2009	Ciarrocca email re Sling thoughts and next steps 11-13-08.doc	ETH.MESH.09951087	ETH.MESH.09951090
8/7/2009	Email Severine Timoner Fortin to Valerie Emperado et al. re For Information - lot of TVT used for Deleval's tests	ETH.MESH.09951106	ETH.MESH.09951107
2/27/2009	Ciarrocca email chain re MiniMe discussion at the board meeting	ETH.MESH.09951746	ETH.MESH.09951747
3/31/2009	Email Piet Hinoul to Katrin Elbert re MiniTVTO	ETH.MESH.09952163	ETH.MESH.09952164
3/31/2009	Email Katrin Elbert to Piet Hinoul RE: MiniTVTO	ETH.MESH.09952168	ETH.MESH.09952169
9/25/2009	Savidge S email chain re TVTO Mini IFU questions	ETH.MESH.09952714	ETH.MESH.09952715
8/8/2009	Hinoul email chain re For Information - lot of TVT used for Deleval's tests	ETH.MESH.09954485	ETH.MESH.09954486
4/24/2009	Email Katrin Elbert to Anna-Caroline Cornec re Mesh strip for Mini-TVT O	ETH.MESH.09955374	ETH.MESH.09955374
8/27/2009	Timoner Fortin email re Mini-O Raw material proposed by Suppliers for button aid	ETH.MESH.09955464	ETH.MESH.09955464
1/7/2009	Total Petrochemicals Certificate N° 9	ETH.MESH.09955474	ETH.MESH.09955479
3/2/2010	Elbert email chain re first draft equivalence Abrevo	ETH.MESH.09956434	ETH.MESH.09956437
4/23/2009	Mini TVT-O Team Meeting	ETH.MESH.09956613	ETH.MESH.09956614
5/15/2009	Email Katrin Elbert to Henri Decloux re Last week's Medi-Line visit	ETH.MESH.09957926	ETH.MESH.09957927

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Date	Description	Bates - Begin	Bates - End
8/7/2009	Email Henri Decloux to Severine Timoner Fortin re Quote for sample production	ETH.MESH.09958050	ETH.MESH.09958051
6/15/2009	Subramanian D email chain re Mini TVTO HE1 assessment	ETH.MESH.09960437	ETH.MESH.09960439
10/4/2010	Elbert K email chain re hold for Abbrevo Lessons Learned	ETH.MESH.09970762	ETH.MESH.09970762
12/6/2011	PLT 12 month post-launch close out PPT - slide 17 Executive Summary.	ETH.MESH.09977270	ETH.MESH.09977271
4/10/2011	Feinberg email chain re TVTO PA full team meeting minutes, Thursday April 7th	ETH.MESH.09982887	ETH.MESH.09982888
12/6/2010	Patel email chain re TVT+M mesh question	ETH.MESH.09983201	ETH.MESH.09983201
	510(k) Premarket Notification GYNECARE TVTO-OA Continence System	ETH.MESH.09984519	ETH.MESH.09984576
	Abbrevo Lessons Learned Pre-Survey Results	ETH.MESH.09985777	ETH.MESH.09985777
4/16/2008	Notes - Post Mini TVT Procedure Discussion	ETH.MESH.10003595	ETH.MESH.10003603
9/28/2012	Letter Benjamin R. Fisher PhD (Department of Health & Human Services) to Susan Lin re Gynecare TVT Abbrevo Continence System K100936 re marketing device	ETH.MESH.10039685	ETH.MESH.10040061
4/3/2012	Beccia N email chain re Alerte TVT Abbrevo	ETH.MESH.10051284	ETH.MESH.10051286
4/3/2012	Pitts email chain re ALERTE TVT ABBREVO	ETH.MESH.10051331	ETH.MESH.10051333
11/8/2010	Innovation Council agenda	ETH.MESH.10132609	ETH.MESH.10132620
7/15/2009	Email Brian Langen to Vincenza Zaddem re Plus-M payment for Mel Anhalt	ETH.MESH.10133116	ETH.MESH.10133116
7/19/2013	Clinical Evaluation Report Gynecare TVT Family of Products	ETH.MESH.10150515	ETH.MESH.10150849
	Ulmsten - Anesthesiological routines for the TVT Procedure	ETH.MESH.10181793	ETH.MESH.10181797
4/23/2001	Ulmsten ltt Ostergard re Cannes meeting	ETH.MESH.10181921	ETH.MESH.10181922
	TVT Update Report on Proposed Changes	ETH.MESH.10182456	ETH.MESH.10182461
	Angelini, Byca, Montanino Gynecare Europena Marketing Plan	ETH.MESH.10183005	ETH.MESH.10183061
2/19/2008	Field Visit Letter Jill Lopez Sales Rep	ETH.MESH.10215453	ETH.MESH.10215458
8/17/2000	Slusser email chain re AUGS lecture/content of discussion	ETH.MESH.10216874	ETH.MESH.10216875
4/6/2011	Hoffman S email chain re 6 weeks into Abbrevo Launch	ETH.MESH.10224489	ETH.MESH.10224490
8/17/2009	Prine email chain re TVT promotion Slam Dunk Winners	ETH.MESH.10227358	ETH.MESH.10227359
5/14/2010	Barendse email re TVT Exact Meeting Follow-up	ETH.MESH.10232709	ETH.MESH.10232709
8/1/2009	2009 Field Visit Letter	ETH.MESH.10233144	ETH.MESH.10233148
12/9/2010	Prine email chain re New GYNEARE RVT ABBREVO sales literature and DVD NOW AVAILABLE	ETH.MESH.10237693	ETH.MESH.10237695
5/3/2013	Hinoul CER Gynecare TVT Family of Products	ETH.MESH.10287104	ETH.MESH.10287439

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Date	Description	Bates - Begin	Bates - End
4/26/2006	Damotte email chain re Laser cut TVT - Surgeon's Preference Evaluation	ETH.MESH.10302266	ETH.MESH.10302267
4/10/2006	Amendment 1 Protocol 300-05-xxx, An Evaluation of the GYNECARE TVT * Tension-free Support for Incontinence and GYNECARE TVT Obturator* System Tension-free Support for Incontinence with Laser Cut Mesh	ETH.MESH.10302268	ETH.MESH.10302279
	An Evaluation of the application of the GYNECARE TVT Obturator* System Tension-free Support for Incontinence with Laser Cut Mesh - Protocol - Sha and Buchon	ETH.MESH.10372554	ETH.MESH.10372564
	Email Christopher Teasdale to Brian Luscombe re FW: Design Validation Surgeons with partial attachment	ETH.MESH.10525611	ETH.MESH.10525612
	TVT Improvement Project Conference Call	ETH.MESH.10591803	ETH.MESH.10591804
7/21/1998	Kaminski email chain re TVT Project Plan	ETH.MESH.10591870	ETH.MESH.10591870
9/30/2013	Angelini Browse JJEDS Object Detail form	ETH.MESH.10591939	ETH.MESH.10591949
2/19/2008	Final Report Evaluation of Area Weight, PP Amount, Tensile Strength	ETH.MESH.10616895	ETH.MESH.10616956
	Gynecare TVT Abbrevio Class III Licence Amendment Application	ETH.MESH.10630324	ETH.MESH.10630449
2/8/2011	Braskem MSDS C4001 Polypropylene	ETH.MESH.10630803	ETH.MESH.10630808
6/19/2009	Sunoco MSDS 2009	ETH.MESH.10630809	ETH.MESH.10630813
4/6/2010	Elbert K email chain re CO-0022344 for your review; Target Approval 4-12-2010 12:00:00 AM EDT	ETH.MESH.10632641	ETH.MESH.10632644
	Young email chain re IFU	ETH.MESH.10632650	ETH.MESH.10632653
3/20/2013	Revision History of MS-0000108	ETH.MESH.10633520	ETH.MESH.10633528
8/4/2011	Gynecare RVTO-OA - Request for Withdrawal of 510k	ETH.MESH.10635251	ETH.MESH.10635515
8/4/2011	TOPA 510k signed full	ETH.MESH.10635251	ETH.MESH.10635515
7/1/1999	Irby, Will - Incontinence/Pelvic Floor Management GYNECARE TVT Tension-free Support for Incontinence 2000 Marketing Plan	ETH.MESH.10657926	ETH.MESH.10657941
4/21/2011	Frost K email re 2011 Incontinence & Pelvic floor REcap	ETH.MESH.10818812	ETH.MESH.10818813
3/31/2011	EWHU: Faculty Training - Sonoma CA Agenda	ETH.MESH.10818814	ETH.MESH.10818814
4/1/2011	Ethicon 2011 Incontinence & Pelvic Floor Summit agenda	ETH.MESH.10818815	ETH.MESH.10818816
	Boston Scientific Slings presentation	ETH.MESH.10958575	ETH.MESH.10958586
2/24/2006	Lamont D Memo re TVT Laser Cut Mesh (LCM) Risk Analysis Summary	ETH.MESH.10984358	ETH.MESH.10984359
8/30/2011	Samuel S email re Mesh Data	ETH.MESH.11175841	ETH.MESH.11175842
	The Science of "What's Lift Behind" . . . presentation	ETH.MESH.11175843	ETH.MESH.11175843
	TVT Complication comparison matrix	ETH.MESH.11175844	ETH.MESH.11175844

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	TVT Abbrevio marketing poster	ETH.MESH.11175863	ETH.MESH.11175863
	Gynecare TVT Exact Gynecare TVT Tension-free Support for Incontinence Clinical Data Presentation	ETH.MESH.11175864	ETH.MESH.11175864
4/6/2010	Email Katrin Elbert to Sheelu Samuel re FW: CO-0022344 for your review; Target Approval 04-12-2010 12:00:00 AM EDT	ETH.MESH.11205022	ETH.MESH.11205027
6/9/1999	Hoepffner email chain re Trip report -- meeting with Dr. Ulstem	ETH.MESH.11283949	ETH.MESH.11283951
6/2/1999	Chen Stockholm Trip Report	ETH.MESH.11283950	ETH.MESH.11283951
5/3/1999	Lehe email re Reisebericht: TVT - Brainstorming (PD 98/5)	ETH.MESH.11283974	ETH.MESH.11283974
07/??/12	FDA Communication re PS120095 GYNECARE TVT Secur System - Amended: 05032012	ETH.MESH.11333804	ETH.MESH.11333805
8/10/1990	Five Year Report re Ten Year In Vivo Suture Study	ETH.MESH.11336474	ETH.MESH.11336487
11/5/2010	Cecchini email chain re Ethicon DVD	ETH.MESH.11336648	ETH.MESH.11336648
	Risk Assessment Summary for Products in the Gynecare TVT Secur System - Revision Hx for 100146510	ETH.MESH.11353422	ETH.MESH.11353439
??/??/10	TVT Abbrevio Physian Brochure -The efficacy she needs with less mesh	ETH.MESH.11434264	ETH.MESH.11434272
1/1/2011	Briefing Documents - Operation Abbrevio	ETH.MESH.11434367	ETH.MESH.11434379
10/6/2011	Email Libby Lewis to Mary Byerly re Western Region Needs	ETH.MESH.11445493	ETH.MESH.11445494
5/16/2011	Bernal O email chain re TVT Abbrevio Eval	ETH.MESH.11445930	ETH.MESH.11445931
1/30/2005	Castillo email chain re Oscar -- The latest fiasco	ETH.MESH.11474337	ETH.MESH.11474337
8/7/2012	Doyle email chain re Surgeon request for follow up 10100175641	ETH.MESH.11529265	ETH.MESH.11529266
4/1/2011	Gerin-Roze email chain re TVT-S Lot related to NCR11-01867	ETH.MESH.11770891	ETH.MESH.11770892
9/16/2002	Email Shannon Campbell to Shelley Copeland, et al. re Ft. Worth Advanced TVT dinner feedback	ETH.MESH.11773498	ETH.MESH.11773499
3/31/2011	Phillips, K email re Lack of quality engineering support for Prosima+M	ETH.MESH.11790162	ETH.MESH.11790162
	TVT Family of Products Sales Rep Promotion TVT Fast Break	ETH.MESH.11917445	ETH.MESH.11917450
3/10/2006	Urology University March 10-11, 2006	ETH.MESH.11920108	ETH.MESH.11920110
1/26/2009	Issue Report	ETH.MESH.11985160	ETH.MESH.11985164
	Licensing Agreement between Universite De Liege and Ethicon, Inc.	ETH.MESH.12002262	ETH.MESH.12002280
6/1/2001	Angelini L email re TVT improvements	ETH.MESH.12002601	ETH.MESH.12002601
	Angelini L email re Ulmsten Consultant Agreement	ETH.MESH.12002845	ETH.MESH.12002845
	Ulmsten draft Consulting Agreement	ETH.MESH.12002847	ETH.MESH.12002860

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5/16/1997	Report on Expert Meeting	ETH.MESH.12006257	ETH.MESH.12006259
	Ulmsten Consulting Agreement	ETH.MESH.12006763	ETH.MESH.12006783
2/1/1999	Norrie, Rowan Product Development Manager, Ethicon Limited, Scotland - The Use of Mesh in Gynaecology (Focus on TVT and Gynemesh) Report	ETH.MESH.12008995	ETH.MESH.12009004
8/18/1998	Rowan email re GyneMesh II New Mesh Design w/attachment	ETH.MESH.12009027	ETH.MESH.12009035
	TVT Improvement Project conference call notes	ETH.MESH.12009079	ETH.MESH.12009081
6/13/1997	Ulmsten Preliminary report of Multicentre Study on TVT	ETH.MESH.12009095	ETH.MESH.12009101
9/13/1999	Lehe email chain re TVT Blue	ETH.MESH.12009257	ETH.MESH.12009257
7/14/1999	Hoepffner email re Marketing Requirements for TVT improvement team	ETH.MESH.12009262	ETH.MESH.12009262
6/18/1999	Angelini email chain re Development Strategy	ETH.MESH.12009276	ETH.MESH.12009277
3/15/2011	Elaine Wise Product Monograph	ETH.MESH.12627553	ETH.MESH.12627577
4/3/2012	Prine G email chain re Alerte TVT Abbrevio	ETH.MESH.12730858	ETH.MESH.12730860
	Memo re Prolene Explants Study Meeting Minutes	ETH.MESH.12831407	ETH.MESH.12831408
8/5/2013	Amin email chain re HPG Pelvic Floor RFP	ETH.MESH.12877116	ETH.MESH.12877117
	RFI Instructions	ETH.MESH.12877118	ETH.MESH.12877118
9/17/2013	Librojo email chain re Copy Review Exception	ETH.MESH.12906504	ETH.MESH.12906506
11/7/2013	Jacobs email chain re defect to harms map	ETH.MESH.12907174	ETH.MESH.12907174
	Spreadsheet Revision History - Defect to Harms Map	ETH.MESH.12907175	ETH.MESH.12907175
6/21/2013	Weisberg email chain re TVT mesh elongation FW: Dr. Kenny Maslow	ETH.MESH.12910023	ETH.MESH.12910026
6/21/2013	Weisberg email chain re TVT mesh elongation FW: dr. Kenny Maslow	ETH.MESH.12910023	ETH.MESH.12910026
6/21/2013	Weisbert email chain re TVT mesn elongation FW: Dr. Kenny Maslow	ETH.MESH.12910030	ETH.MESH.12910032
6/25/2013	Weisberg email chain re TVT mesh enlongation - Redacted	ETH.MESH.12910111	ETH.MESH.12910113
8/28/2013	Hinoul email re MIR TVT - ilioninguinal pain w/attachment	ETH.MESH.12913351	ETH.MESH.12913356
8/29/2005	Physician form letter	ETH.MESH.12933182	ETH.MESH.12933183
5/6/2008	Form letter re TVTS4-Gynecare TVT Secur System	ETH.MESH.12939705	ETH.MESH.12939705
3/2/2004	Burns email chain re Remainder on BLUE mesh!	ETH.MESH.13204333	ETH.MESH.13204334
7/5/2010	Email Kathie Chen to Darlene Jane Kyle, et al. re Product Complaint CC1007005-Taiwan	ETH.MESH.13204508	ETH.MESH.13204521
8/2/2010	Email Darlene Jane Kyle to Kathie Chen re Product Complaint CC1007047&CC1007048-Taiwan (TVTO:810081)	ETH.MESH.13206130	ETH.MESH.13206134
3/20/2013	Connaughton email chain re New ligitation TVT	ETH.MESH.13208194	ETH.MESH.13208196

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8/17/2010	Email Celine Heramza to Carolyn Brennan re Assignment "Product evaluation" has been closed for Issue #:10100122655	ETH.MESH.13210344	ETH.MESH.13210346
6/2/2011	Holloway email chain re TVT-O medial and lateral leg pain - MIR CHATS # 10100143432	ETH.MESH.13213760	ETH.MESH.13213766
	Kyle Itt Chen re Customer's experience with TVT-O	ETH.MESH.13226457	ETH.MESH.13226457
5/23/2013	Connaughton email chain re New litigation	ETH.MESH.13259844	ETH.MESH.13259845
2/15/2013	Connaughton email chain re New litigation Prolift & TVT	ETH.MESH.13274846	ETH.MESH.13274847
2/15/2013	Connaughton email chain re new litigation Prolift & TVT	ETH.MESH.13274855	ETH.MESH.13274856
4/29/2011	Holloway email chain re Removal of TVT-O system due to severe neuropathic leg pain - MIR	ETH.MESH.13284086	ETH.MESH.13284088
8/19/2013	Finch email chain re New litigation TVT-S	ETH.MESH.13292806	ETH.MESH.13292807
9/21/2013	Gallo email chain re new litigation TVT	ETH.MESH.13296239	ETH.MESH.13296240
1/11/2013	Chung email chain re Gynecare RFP	ETH.MESH.13374555	ETH.MESH.13374558
	RFI Instructions	ETH.MESH.13374559	ETH.MESH.13374559
	Draft Template: DRM for Device Functionality (Performance & Safety)	ETH.MESH.13376661	ETH.MESH.13376868
8/6/2012	Work Instructions for In-Process & Finished Goods Defect Classifications for Ethicon Products, Appendix 8 - Mesh	ETH.MESH.13376756	ETH.MESH.13376758
8/6/2012	Primary Blister Defect Definitions and Classifications Release Level: 4. Production	ETH.MESH.13376759	ETH.MESH.13376768
6/13/2013	Journot email chain re Design Impact assessment ADAPTIV - Creation of change project	ETH.MESH.13457716	ETH.MESH.13457718
	Vailhe email chain re Pore Size of Gynemesh PS and TVT Tapes	ETH.MESH.13523693	ETH.MESH.13523696
10/1/2012	Gynecare TVT Abbrevio Salees Aid TVTA 325-12	ETH.MESH.13681528	ETH.MESH.13681528
3/25/2012	The efficacy she needs with less mesh	ETH.MESH.13681529	ETH.MESH.13681532
5/22/2013	GGM Blue Database Export TVT Obturator Brochure	ETH.MESH.13700031	ETH.MESH.13700032
1/8/2014	TVTO_366_13_TVT Obturator Brochure	ETH.MESH.13700033	ETH.MESH.13700037
6/19/2013	GGM Blue Database Export Project ID: 417127 TVTO-426-13	ETH.MESH.13704931	ETH.MESH.13704932
4/26/2013	Clinical Expertise - The Evolution of Sub-urethral Slings for the Surgical Corrector of Female Stress Urinary Incontinence (SUI) Obturator	ETH.MESH.13739540	ETH.MESH.13739540
	Check Liste D'Inspection QQualite	ETH.MESH.13797826	ETH.MESH.13797830
	Secant Knitting Mesh Evaluation Revision A	ETH.MESH.13825635	ETH.MESH.13825639
	Validation strategy for TVT retropubic refresh (TVT RR) manufacturing process at Neuchatel	ETH.MESH.13840459	ETH.MESH.13840466

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	Check Liste D'Inspection Qualite	ETH.MESH.13860322	ETH.MESH.13860342
	Check Liste D'Inspection Qualite Final TVT/TVT-AA	ETH.MESH.13869615	ETH.MESH.13869634
3/11/2012	PV Minutes of TAM meeting	ETH.MESH.13886781	ETH.MESH.13886782
7/12/2010	Poulot email chain re BHR EWHU 3413118, 398077, 3405428	ETH.MESH.13896042	ETH.MESH.13896043
3/17/2010	Hibon email re TVT-Standard production stopped due to metallic particle on needles	ETH.MESH.13906093	ETH.MESH.13906093
8/17/2010	Jaccard email chain re Particles in production w/attachment	ETH.MESH.13907355	ETH.MESH.13907355
	Spreadsheet	ETH.MESH.14221357	ETH.MESH.14221357
??/??/11	Ethicon Neuchâtel A changing Product Protfolio	ETH.MESH.14273633	ETH.MESH.14273668
1/21/2013	Tait email chain re Non conform lids	ETH.MESH.14348386	ETH.MESH.14348388
2/16/2005	Copy review submission form - Hernia ad; Proceed Mesh. ULTRAPRO mesh and PROLENE hernia system	ETH.MESH.14409737	ETH.MESH.14409741
2/2/2005	McCabe Gynecare TVT Mesh Brochure copy review submission form	ETH.MESH.14410478	ETH.MESH.14410484
4/8/1999	Toth Memo to Copy Review Team re New Construction PROLENE polypropylene mesh Sales Aid and Demo Device	ETH.MESH.14410703	ETH.MESH.14410741
5/4/1999	Toth email chain re New Construction PROLENE polypropylene mesh Pre-Launch Memo w/attachment	ETH.MESH.14410846	ETH.MESH.14410851
6/24/1999	Toth, JL Memo to Copy Review Team re TVT Tension-free Vaginal Pate Press Briefing Presentation	ETH.MESH.14411026	ETH.MESH.14411040
10/1/2003	Gynecare TVT AUGS & Competitive Update - copy review submission form	ETH.MESH.14415287	ETH.MESH.14415309
3/17/2004	Gynecare Copy Review Submission Form submitted by Giselle M. Bonett re Gynecare Gynemesh PS	ETH.MESH.14416076	ETH.MESH.14416081
3/3/2004	Gynecare Copy Review - Inside Gynecare Vol II, #5	ETH.MESH.14416182	ETH.MESH.14416221
4/14/2004	Copy Review Submission Frm - MoniTorr, TVT-O, CORLINK, ProPen, MultiPass	ETH.MESH.14416898	ETH.MESH.14416959
6/11/2009	Divilio Memo re The Use of Mesh in Hernia Repair	ETH.MESH.14442958	ETH.MESH.14442976
4/17/2006	Kammerer G Memo re Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT Laser Cut Mesh	ETH.MESH.14450438	ETH.MESH.14450442
	Work Instructions for In-Process & Finished Goods Defect Classifications for Ethicon Products, Appendix 1 - Assembly Errors	ETH.MESH.14450971	ETH.MESH.14451103

Date	Description	Bates - Begin	Bates - End
	Work Instructions for In-Process & Finished Goods Defect Classifications for Ethicon Products, Appendix 8 - Mesh	ETH.MESH.14451057	ETH.MESH.14451059
	Primary Blister Defect Definitions and Classifications RElease Level: 4 Production	ETH.MESH.14451060	ETH.MESH.14451068
	Spreadsheet	ETH.MESH.14471186	ETH.MESH.14471186
6/1/2007	Trending analysis meeting presentation	ETH.MESH.14708810	ETH.MESH.14708848
03/??/07	CAPA 070015 Trending and tracking system - presentation	ETH.MESH.14708986	ETH.MESH.14709011
4/6/2010	Taggart D email chain re CO-002344 for your review: Target Approval 04-12-2010 12:00 AM EDT	ETH.MESH.14819286	ETH.MESH.14819290
	Millicker email chain re addtl info - TVT & Prosima	ETH.MESH.14852589	ETH.MESH.14852590
6/5/2013	McNelis email re new litigation TVT & Prosima	ETH.MESH.14852591	ETH.MESH.14852592
1/6/2014	Killins email chain re Addtl info - new litigation TVT & Prosima	ETH.MESH.14852593	ETH.MESH.14852595
11/9/2013	Finch email re new litigation TVT	ETH.MESH.14896228	ETH.MESH.14896229
2/4/2014	Piper email chain re Addtl info	ETH.MESH.14896230	ETH.MESH.14896232
2/7/2014	Tran email chain re addtl info 1/30/14	ETH.MESH.14896233	ETH.MESH.14896235
	Complaint PI1E8VOWN	ETH.MESH.14901753	ETH.MESH.14901753
	Millicker email chain re Addtl Info TVT & Prosima	ETH.MESH.14901754	ETH.MESH.14901755
6/5/2013	McNelis email re new litigation TVT & Prosima	ETH.MESH.14901756	ETH.MESH.14901757
1/6/2014	Killins email chain re Addtl info new litigation TVT & Prosima	ETH.MESH.14901758	ETH.MESH.14901760
8/3/2010	Complaint Number: PI1-EWT0A6	ETH.MESH.14908783	ETH.MESH.14908783
7/2/2013	Connaughton email chain re new litigation TVT-O	ETH.MESH.14908784	ETH.MESH.14908785
12/8/2013	Finch email chain re Addtl Info New Litigation Prosima & TVT-O	ETH.MESH.14913573	ETH.MESH.14913575
1/30/2014	Tran email chain re addtl info - Prosima & TVT-O	ETH.MESH.14913576	ETH.MESH.14913578
8/3/2010	Complaint Number: PI1-F8GCTO	ETH.MESH.14967283	ETH.MESH.14967283
7/15/2013	Connaughton email chain re New litigation TVT-O	ETH.MESH.14967284	ETH.MESH.14967285
1/31/2014	Jackson email chain Addtl Info -	ETH.MESH.14967286	ETH.MESH.14967287
12/8/2013	Finch email chain re Addtl Info new litigation Prosima & TVT-O	ETH.MESH.14994654	ETH.MESH.14994656
1/30/2014	Tran email chain re Addtl Info -	ETH.MESH.14994657	ETH.MESH.14994659
11/7/2013	McNelis email new litigation TVT	ETH.MESH.15034561	ETH.MESH.15034562
1/30/2013	CAPA-002157	ETH.MESH.15137959	ETH.MESH.15137967
9/26/2013	CAPA File - Protocol to migrate CAPAs from PLM to ETQ Application	ETH.MESH.15137968	ETH.MESH.15137968
	CAPA130022 - Summary Report - particles	ETH.MESH.15137969	ETH.MESH.15137978

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2/18/2013	Journot memo re CAPA130022 - Defective percentage justification	ETH.MESH.15137979	ETH.MESH.15137979
	CAOA 130022 - Failure Investigation - particles	ETH.MESH.15137980	ETH.MESH.15137983
3/8/2013	CAPA#130022 - Repetition of NCR for particles - Team Meeting Minutes	ETH.MESH.15137986	ETH.MESH.15137987
	Ethicon, Inc. Book No. 3077	ETH.MESH.15143734	ETH.MESH.15143821
	ETHICON - Rules for Laboratory Notebooks	ETH.MESH.15144988	ETH.MESH.15145028
1/20/1988	Report: Quebec Explants	ETH.MESH.15144996	ETH.MESH.15144996
2/23/2011	Smith email chain re PC 10-029	ETH.MESH.15257127	ETH.MESH.15257128
11/2/2010	Process Qualification of FSMK0238 Revision 1	ETH.MESH.15257129	ETH.MESH.15257155
5/20/2009	Email Stale Kvitle to Jean DeLeval, et al. re Mini Me follow up from our visit	ETH.MESH.15285672	ETH.MESH.15285672
12/2/2011	Henderson email - Gynecologic and Obstetric Investigation (1983) Abstract	ETH.MESH.15354959	ETH.MESH.15354959
	Smith email chain re Pore Size of Gynemesh PS and TVT Tapes	ETH.MESH.15362144	ETH.MESH.15362147
2/18/2003	Universite de Liege and Ethicon Licensing Agreement	ETH.MESH.15363068	ETH.MESH.15363085
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406846	ETH.MESH.15406856
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406857	ETH.MESH.15406859
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406860	ETH.MESH.15406861
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406862	ETH.MESH.15406863
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406864	ETH.MESH.15406866
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406867	ETH.MESH.15406868
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406869	ETH.MESH.15406870
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406871	ETH.MESH.15406873
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406874	ETH.MESH.15406876
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406877	ETH.MESH.15406879
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406880	ETH.MESH.15406881
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406882	ETH.MESH.15406883
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406884	ETH.MESH.15406885
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406886	ETH.MESH.15406887
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406888	ETH.MESH.15406889
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406890	ETH.MESH.15406892
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406893	ETH.MESH.15406894
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406895	ETH.MESH.15406896
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406897	ETH.MESH.15406899
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406900	ETH.MESH.15406902
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406903	ETH.MESH.15406905
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406906	ETH.MESH.15406909
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406910	ETH.MESH.15406912
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406913	ETH.MESH.15406915
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406916	ETH.MESH.15406919
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406920	ETH.MESH.15406921
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406922	ETH.MESH.15406923
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406924	ETH.MESH.15406926

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	Guidoin Lab Notebook Page/Image	ETH.MESH.15406927	ETH.MESH.15406928
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406929	ETH.MESH.15406930
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406931	ETH.MESH.15406932
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406933	ETH.MESH.15406934
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406935	ETH.MESH.15406936
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406937	ETH.MESH.15406938
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406939	ETH.MESH.15406941
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406942	ETH.MESH.15406943
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406944	ETH.MESH.15406945
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406946	ETH.MESH.15406947
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406948	ETH.MESH.15406949
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406950	ETH.MESH.15406951
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406952	ETH.MESH.15406953
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406954	ETH.MESH.15406955
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406956	ETH.MESH.15406957
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406958	ETH.MESH.15406960
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406961	ETH.MESH.15406962
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406963	ETH.MESH.15406964
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406965	ETH.MESH.15406966
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406967	ETH.MESH.15406968
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406969	ETH.MESH.15406970
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406971	ETH.MESH.15406971
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406972	ETH.MESH.15406972
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406973	ETH.MESH.15406973
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406974	ETH.MESH.15406974
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406975	ETH.MESH.15406975
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406976	ETH.MESH.15406976
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406977	ETH.MESH.15406977
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406978	ETH.MESH.15406978
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406979	ETH.MESH.15406981
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406982	ETH.MESH.15406984
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406985	ETH.MESH.15406986
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406987	ETH.MESH.15406988
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406989	ETH.MESH.15406989
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406990	ETH.MESH.15406991
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406992	ETH.MESH.15406993
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406994	ETH.MESH.15406997
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406998	ETH.MESH.15406999
	Email Lissette Caro-Rosado to Ronald Horton, et al. RE: KOL Usage	ETH.MESH.15426052	ETH.MESH.15426053
4/15/2008	Trip Notes	ETH.MESH.15433760	ETH.MESH.15433773
10/2/2003	Arnaud email re Pr de LEVAL expenses	ETH.MESH.15928345	ETH.MESH.15928345
	Clinical Strategy Project Scion PP & Scion PA - annotated	ETH.MESH.15928408	ETH.MESH.15928411
3/23/1983	Guidoin Lab Notebook Page/Image	ETH.MESH.15955438	ETH.MESH.15955473
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958336	ETH.MESH.15958395

## DOCUMENTS

Date	Description	Bates - Begin	Bates - End
3/17/1982	Guidoin Lab Notebook Page/Image	ETH.MESH.15958396	ETH.MESH.15958399
5/25/1983	Guidoin Lab Notebook Page/Image	ETH.MESH.15958400	ETH.MESH.15958404
11/7/1984	Guidoin Lab Notebook Page/Image	ETH.MESH.15958405	ETH.MESH.15958407
9/27/1984	Guidoin Lab Notebook Page/Image	ETH.MESH.15958408	ETH.MESH.15958409
3/25/1983	Guidoin Lab Notebook Page/Image	ETH.MESH.15958410	ETH.MESH.15958432
8/14/1984	Guidoin Lab Notebook Page/Image	ETH.MESH.15958433	ETH.MESH.15958444
3/11/1985	Guidoin Lab Notebook Page/Image	ETH.MESH.15958445	ETH.MESH.15958451
11/5/1984	Guidoin Lab Notebook Page/Image	ETH.MESH.15958452	ETH.MESH.15958469
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958470	ETH.MESH.15958477
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958478	ETH.MESH.15958480
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958481	ETH.MESH.15958485
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958486	ETH.MESH.15958491
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958492	ETH.MESH.15958494
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958495	ETH.MESH.15958502
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958503	ETH.MESH.15958507
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958508	ETH.MESH.15958509
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958510	ETH.MESH.15958511
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958512	ETH.MESH.15958517
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958518	ETH.MESH.15958523
3/2/1981	Guidoin Lab Notebook Page/Image	ETH.MESH.15958524	ETH.MESH.15958524
	Consulting Agreement between Dr. Douglas Grier and Ethicon	ETH.MESH.16260624	ETH.MESH.16260629
3/4/2010	EWHU 2009 Awards Ceremony	ETH.MESH.16263696	ETH.MESH.16263715
??/??/12	DSL Clinical Article Waltregny - New Surgical Technique for Tx of SUI TVT-Abbrevio . . .	ETH.MESH.16289560	ETH.MESH.16289569
??/??/13	Patient Brochure	ETH.MESH.16308087	ETH.MESH.16308090
4/7/2014	Dear Dr. Itr re unsolicited request for medical/scientific infomation - Gynecare TVT Abbrevio	ETH.MESH.16354541	ETH.MESH.16354545
2/6/2014	Sedlatschek email chain re Secant Medical Inquiry on Gynecare Mesh Products	ETH.MESH.16357097	ETH.MESH.16357097
1/10/2014	Hinoul P email re Abbrevio MIR	ETH.MESH.16359412	ETH.MESH.16359412
	Dr. Ramashandha Hosmane Itr	ETH.MESH.16359413	ETH.MESH.16359416
4/11/2014	Hinour P email chain re TVT Abbrevio medical information request	ETH.MESH.16359598	ETH.MESH.16359598
2/7/2008	Kahlson H email chain re Conversion to Laset Cut TVT	ETH.MESH.16416002	ETH.MESH.16416004
??/??/12	Evaluation of the Fixation of Gynecare TVT Abbrevio Continence System as Compared to Gynecare TVT Obturatory System Tension-Free Support for Incontinence in Human Cadaveric Model - Presentaiton	ETH.MESH.16426660	ETH.MESH.16426660
	Toglia presentation, The Mesh Story	ETH.MESH.16432550	ETH.MESH.16432550
4/19/2010	Minutes for Project Mini TVTO Design Outputs Design Review	ETH.MESH.16433747	ETH.MESH.16433756
3/9/2011	Papas N email chain re AUGS Abstract	ETH.MESH.16434349	ETH.MESH.16434352

## DOCUMENTS

Date	Description	Bates - Begin	Bates - End
4/5/2012	Luscombe B email re Brand Team for Inc POP	ETH.MESH.17556486	ETH.MESH.17556487
4/2/2012	Barnes C email chain re Ethicon Gynecare Innovations Event	ETH.MESH.17556496	ETH.MESH.17556497
4/12/2012	Ethicon Gynecare Innovations flyer	ETH.MESH.17556498	ETH.MESH.17556498
4/3/2012	Barnes C email chain re ACT REQ: Urgent quick need request	ETH.MESH.17556511	ETH.MESH.17556511
4/4/2012	Langen B email re SMII Welcome Letter	ETH.MESH.17556512	ETH.MESH.17556512
4/12/2012	Langen B letter re Sales Mastery II	ETH.MESH.17556513	ETH.MESH.17556513
4/27/2012	Barnes C email chain re Ty Erickson Adobe Connect's with Abbrevio	ETH.MESH.17556538	ETH.MESH.17556539
7/22/2011	Chahal R email chain re Umaima Jamaluddin procedure questions	ETH.MESH.17556556	ETH.MESH.17556556
	Chahal email re price quote	ETH.MESH.17556577	ETH.MESH.17556577
??/??/11	2011 Price List	ETH.MESH.17556578	ETH.MESH.17556579
	Chahal R email chain re Lucente Consent Form	ETH.MESH.17556580	ETH.MESH.17556581
10/??/08	IFPM position on FDA notification	ETH.MESH.17556582	ETH.MESH.17556582
	Physician Consultation Visit Regarding Decision for Surgery Form	ETH.MESH.17556583	ETH.MESH.17556583
2/6/2012	Chahal R email re Booking Confirmation Jeremy William Aaron - Phoenix, Feb 13	ETH.MESH.17556591	ETH.MESH.17556593
4/3/2012	Chahal R email chain re ACT REQ Urgent quick need	ETH.MESH.17556598	ETH.MESH.17556598
1/1/1970	Chahal email re highlights from Denver TVT Abbrevio Lab	ETH.MESH.17556601	ETH.MESH.17556601
6/7/2011	Jones S email re conference call on converting an outside in user to Abbrevio	ETH.MESH.17556602	ETH.MESH.17556603
7/6/2001	Dormier E email chain re Vypro vs Soft Prolene Mesh for Pelvic Floor Repair	ETH.MESH.17606501	ETH.MESH.17606502
3/27/2014	Rodriguez email chain re Secant Medical Inquiry on Gynecare Mesh Products	ETH.MESH.17619399	ETH.MESH.17619405
1/9/2014	Corrado email re QRB presentation	ETH.MESH.17640736	ETH.MESH.17640767
4/14/2014	PQI Revision 10	ETH.MESH.17642669	ETH.MESH.17642686
4/14/2000	Hellberg communication re Product Complaint Form	ETH.MESH.17661336	ETH.MESH.17661499
4/5/2000	Angleitner email chain re TVT Product complaint w/handwritten notes	ETH.MESH.17661347	ETH.MESH.17661347
4/5/2000	Angleitner email chain re TVT Product Complaint	ETH.MESH.17661347	ETH.MESH.17661347
5/19/2014	Rodriguez email chain re UPDATE to Escalation Notice - Section 39 Request - TVT, Gynemesh PS & Artisyn Y-Shared Mesh	ETH.MESH.17777759	ETH.MESH.17777762
2/7/2014	Sedlatschek email re Secant Medical Inquiry on Gynecare Mesh Products	ETH.MESH.17777763	ETH.MESH.17777768
	Complete Mulberry R&D Team and Launch team Webcast - Accomplishments/Individual team recognition	ETH.MESH.17789897	ETH.MESH.17789898

## DOCUMENTS

Date	Description	Bates - Begin	Bates - End
3/15/2011	Kaminski email chain re Proxima Preparation	ETH.MESH.18846146	ETH.MESH.18846147
4/14/2014	Elbert email chain re Candad - TVT RFQ	ETH.MESH.19125383	ETH.MESH.19125385
10/2/2014	Smith email re TVT Products	ETH.MESH.19125531	ETH.MESH.19125531
6/4/2012	PFT / TVT Secur Discontinuation: Current State - Presentation	ETH.MESH.19223769	ETH.MESH.19223773
3/17/2010	Ullman email chain re "Take Back Share" - Feb Update	ETH.MESH.19306944	ETH.MESH.19306946
9/24/2008	Email Marcus Oldelehr to Brian Flynn re Flynn visit 10/23	ETH.MESH.19354118	ETH.MESH.19354119
6/28/2005	Objectives for Jennifer - May-August	ETH.MESH.19356913	ETH.MESH.19356915
8/8/2011	TOPA withdraw confirmation	ETH.MESH.20006789	ETH.MESH.20006791
	Revision Hx for pFMEA-0000497	ETH.MESH.21488624	ETH.MESH.21488636
1/16/2012	Draft - Uniform three dimensional tissue scaffold of absorbable and non-absorbable materials	ETH.MESH.22140231	ETH.MESH.22140234
8/16/2011	Draft - Matrix 1,2 -- Tissue Bulking Material, Methods, and Devices (external bulking)	ETH.MESH.22140235	ETH.MESH.22140238
2/19/2011	Mesh Processing Meshes Fabricated from Dissimilar Materials - Summary Document - Draft	ETH.MESH.22140265	ETH.MESH.22140266
6/1/2015	Ethicon UK Gynaecology Complaints email re Customer Ref 2015/005/020/104/005 Request for Information	ETH.MESH.22646295	ETH.MESH.22646296
	Jacobs email chain re TVT Defect to Harm Map	ETH.MESH.22680210	ETH.MESH.22680216
05/??/12	Quality Operation Review Trend Analysis Metrics - presentation	ETH.MESH.22754103	ETH.MESH.22754142
2/27/2014	Revision Hx 100193881	ETH.MESH.22852060	ETH.MESH.22852063
3/26/2003	Arnaud A email chain re Mulberry	ETH.MESH03919404	ETH.MESH03919405
2/28/2005	Everett J Summary Memo for Revision C of the Gynecare PROLIFT Device Design Safety Assessment	ETH-03531	ETH-03567
	History of mesh production and processing	ETH-03877	ETH-03886
	Slide: Selecting the Right Mesh	ETH-50330	ETH-50330
	Check Liste D'Inspection Qualite	ETH-53294	ETH-53294
1/1/2011	2011 Performance and Development Plan Summary for Chahal	ETHMESH.CHAHAL.00000001	ETHMESH.CHAHAL.00000005
4/6/2010	Chahal Employee Secrecy, Intellectual Property, Non-Competition and Non-Solicitation Agreement	ETHMESH.CHAHAL.00000006	ETHMESH.CHAHAL.00000027
	Chahal sales spreadsheets	ETHMESH.CHAHAL.00000028	ETHMESH.CHAHAL.00000048
??/??/11	ChahalHospital Sales Spreadsheet	ETHMESH.CHAHAL.00000044	ETHMESH.CHAHAL.00000048
7/17/2014	Chahal Career Development Profile	ETHMESH.CHAHAL.00000049	ETHMESH.CHAHAL.00000050

## DOCUMENTS

Date	Description	Bates - Begin	Bates - End
5/18/2012	Chahal Employee Profile	ETHMESH.CHAHAL.00000051	ETHMESH.CHAHAL.00000051
1/22/2011	Lewis L - 2011 Field Visit Letter, Chahal	ETHMESH.CHAHAL.00000052	ETHMESH.CHAHAL.00000063
	O'Hara C email re Year End Summay	ETHMESH.CHAHAL.00000064	ETHMESH.CHAHAL.00000065
8/8/2002	O'Hara Employment Eligibility Verification Form	ETHMESH.OHARA.00000001	ETHMESH.OHARA.000000156
8/8/2002	O'Hara personnel file docs	ETHMESH.OHARA.00000157	ETHMESH.OHARA.000000303
07/??/02	O'Hara Application for Employment	ETHMESH.OHARA.00000304	ETHMESH.OHARA.000000312
3/3/2012	O'Hara Employee Profile	ETHMESH.OHARA.00000313	ETHMESH.OHARA.000000314
1/26/2006	Vandenburg 2005 Performance and Development Plan Summary for Christopher O'Hara	ETHMESH.OHARA.00000315	ETHMESH.OHARA.000000321
1/23/2007	Qually 2006 Performance and Development Plan Summary for O'Hara	ETHMESH.OHARA.00000322	ETHMESH.OHARA.000000327
2/4/2008	Ullmann 2007 Performance and Development Plan Summary for O'Hara	ETHMESH.OHARA.00000328	ETHMESH.OHARA.000000333
3/9/2009	Ullmann 2008 Performance and Developmnet Plan Summary for Christopher O'Hara	ETHMESH.OHARA.00000334	ETHMESH.OHARA.000000339
1/1/2009	2009 Performance and Development Plan Summary for Christopher O'Hara	ETHMESH.OHARA.00000340	ETHMESH.OHARA.000000346
2/21/2011	Lewis 2010 Performance and Development Plan Summary for O'Hara	ETHMESH.OHARA.00000347	ETHMESH.OHARA.000000353
1/30/2012	O'Hara 2011 Performance and Development Plan Summary - Libby Lewis	ETHMESH.OHARA.00000354	ETHMESH.OHARA.000000359
5/2/2014	O'Hara Career Development Profile	ETHMESH.OHARA.00000360	ETHMESH.OHARA.000000362
6/21/2001	TVT Recommendations from Dr. Wang - Meeting Minutes of June 21, 2001	HMESH_ETH.00958003	HMESH_ETH.00958005
??/??/03	Contact Points - Nummular allergic contact dermatitis after scabies treatment, R. Kaminska, et al	HMESH_ETH.07269753	HMESH_ETH.07269765
2/18/1998	Liu email chain re Prolene Mesh Redesign	HMESH_ETH_00133261	HMESH_ETH_00133262
2/17/2010	Holste email chain re PP vs PVDF or Pronova	HMESH_ETH_00228961	HMESH_ETH_00228973
09/??/07	Pleiger - Polyamid.nylon MSDS	HMESH_ETH_00660369	HMESH_ETH_00660411
1/16/2001	Dormier email chain re Corporate Product Characterization December Monthly Report	HMESH_ETH_00946830	HMESH_ETH_00946838
6/26/2001	Luscombe email chain re TVT recommendations from Dr. Wang	HMESH_ETH_00958014	HMESH_ETH_00958015

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5/22/2006	"World Premiere" as Ethicon Women's Health & Urology with special guest Bonnie Blair	HMESH_ETH_01840151	HMESH_ETH_01840152
1/6/2005	Mahar email re LCM	HMESH_ETH_01871640	HMESH_ETH_01871642
3/15/2005	Oldelehr M email chain re Kalamazoo TVT Business at Risk	HMESH_ETH_01876389	HMESH_ETH_01876393
3/24/2008	Mahar K email chain re Project SCION Update & Next Steps	HMESH_ETH_01881060	HMESH_ETH_01881062
	Data Review - 120 day results for Scion (TVT+M) Ingrowth Study PSE 10-0126	HMESH_ETH_02041603	HMESH_ETH_02041603
9/16/2010	Interim (28 day) Report, PSE Accession No. 10-0126, Project No. 11730	HMESH_ETH_02041604	HMESH_ETH_02041626
	Marrero email re PPQ Protocol from 5 mil construction	HMESH_ETH_02512521	HMESH_ETH_02512521
3/23/2009	Hinoul Protocol proposition - Modified TVT-O for the treatment of female stress incontinence: anatomical considerations	HMESH_ETH_02571221	HMESH_ETH_02571226
	Stockholm Trip Report	HMESH_ETH_02781707	HMESH_ETH_02781708
2/6/2001	Vypro for Pelvic Floor Repair agenda	HMESH_ETH_02944363	HMESH_ETH_02944364
	Reprint: ULTRAPRO Hernia System: Toward and ideal solution: The Bonheiden experience with a partially absorbable and macroporous bilayer device	HMESH_ETH_03257648	HMESH_ETH_03257655
3/26/2014	Rodriguez email chain re Nilsson 2013	HMESH_ETH_06033196	HMESH_ETH_06033202
5/4/2007	Timmer message re updated Mesh Shrinkage Discussion meeting w/attachments	HMESH_ETH_06509815	HMESH_ETH_06509817
	Text File	HMESH_ETH_06509816	HMESH_ETH_06509816
12/9/2010	Vellucci email chain re Mesh and Biomechanical Data for TVTO-PA 510(k)	HMESH_ETH_07956799	HMESH_ETH_07956800
	Draft AUGS-SUFU Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence	MIL000268	MIL000274
	AUGS/SUFU MUS Task Force Agenda	MIL00282	MIL00282
	Training Videos	PM.00003.m4v	PM.00003.m4v
	Training Videos - Retropubic Implantation Video	PM.00004.m4v	PM.00004.m4v
	Training Videos	PM.00011.m4v	PM.00011.m4v
??/??/14	Total Units Sold Chart	T-1499	T-1499
	Material Safety Data Sheet, Chevron Philips 2004	T-3137	T-3137
	GYNECARE TVT ABBREVO® Continence System _ Ethicon - Science		

## DOCUMENTS

Date	Description	Bates - Begin	Bates - End
06/??/03	Clark Urological Center Newsletter		
3/11/2013	Hellhammer_091113_04 - Designation Run Report		
9/30/2011	FDA - Considerations about Surgical Mesh for SUI		
??/??/03	T 437 om-03 Dirt in paper and paperboard		
1/19/2005	Mechanical v "Machine" - cut Mesh Prepared by Allison London Brown, Gene Kammerer		
	Rule 26 Expert Report of Christina Pramudji, MD		
1/27/2005	US Patent Application Publication US20050021086 20050127		
	Vypro Mesh - Prolene Mesh		
	Study Slides - various testimony		
5/7/2013	GYNECARE TVT ABBREVO - Mesh Placement Sheet for Patient Consult TVTA-357-10 CA Email		
7/25/2003	Patent WO2004019786A1 - Devices for surgical treatment of female urinary inc		
2/5/2014	Exhibit T-3604 LCM sales inside the US		
	TVT product sales		
	Design FMEA: TVT Laser Cut Mesh Project spreadsheet		
	TVT Retropubic Mechanical Cut, US Sales		
	Summary of 63 TVT-O RCTs - Batiste Defense Trial Exhibit		
	Grier with notes T-752		
	TVT-O mechanical cut: 810081, 810081E5		
??/??/13	AUA 2013 Annual Meeting Highlights Voiding Dysfunction/Female Urology		
	Rule 26 Expert Report of Michael Thomas Margolis, MD		
07/??/13	ICS Fact Sheets A Background to Urinary and Faecal Incontinence prepared by the Publications & Communications Committee, July 2013		
	VOC Summary Mini Me - Presentation		
9/8/2011	Advisory meeting transcript - Gaithersburg, MD		
	Ethicon - Incontinence Surgery		
7/28/2009	TVT Mini - O COGS for NPV		
	TVT-O laser cut mesh: 810081L		
	Complication spreadsheet T-3521		
6/28/2014	Management of Mesh Complications AUGS and IUGA 2014 CButrick		
3/13/2011	TVT Patient Brochure Chart - TVT/SUI Patient Brochures		

## DOCUMENTS

Date	Description	Bates - Begin	Bates - End
9/9/2011	Update on Surgical Mesh for Stress Urinary Incontinence (SUI) - FDA Meeting of the Obstetric and Gynecologic Devices Panel		
7/1/2010	FDA 510k communications and filings TVT-abbrevo from FDA		
9/9/2010	2010 FDA Perspective on Surgical Mesh for Stress Urinary Incontinence (SUI)		
	Slide of LW LPR mesh used in pelvic floor		
	Jordi SEM and OM Images		
	Flexibility/Compliance		
	510(k) Submission and Communications for Prosima		
	510(k) Submission and Communications for TVT GYNECARE TVT ABBREVO® Continenence System _ Ethicon		
8/12/2009	US Patent Application Publication De Leval US20090306459		
1/2/2015	GYNECARE TVT ABBREVO® Continenence System _ Ethicon		
2/24/2000	Labelling for Medical Devices by SG1 and endorsed by The Global Harmonization Task Force		
10/??/11	AUA HP Brief - Billing for Sling Revisions and Urethrolisis		
	AUGS-SUFU Position Statement drafts		
5/21/2014	GYNECARE TVT ABBREVO® Continenence System _ Ethicon		
	- European Patent SpecificationEP1542596B1		
6/20/2014	Letter Dr. Aileen Keel to Colleague re Transvaginal mesh implants		
??/??/06	AMS Solutions for Life Preserving Mesh Integrity, Simplifying Tensioning		
6/3/2005	Labelling for Medical Devices by SG1 and endorsed by The Global Harmonization Task Force		
	Neuchatel_Particles in TVTO Blisters		
??/??/14	Webpage "A Solution: Gynecare TVT Tension-free Support for Incontinence"		
	Misc. Medical Records from Dr. Flynn		
7/25/2003	Patent CA2497158C - Devices for surgical treatment of female urinary incontinence		
	CV of Katrin EK Elbert, PhD		
	Medical Staff Update_ Urogynecology center forges ahead with new director, c		
	Gynecare_Professional_Education_Digital_Library		

Date	Description	Bates - Begin	Bates - End
6/9/2014	T-1499 - Product data		
??/??/03	T 437 om -03 Dirt in Paper and Paperboard		
9/8/2011	Surgical Mesh Panel Meeting Summary		
	CV of Scott A Guelcher		
	Ethicon - Incontinence Surgery Types		
	Degradation Slides		
4/17/2007	US7204802 - US Patent De Leval		
	GYNECARE TVT ABBREVO - Mesh Placement Sheet for Patient Consult TVTA-357-10 SD		
9/12/2013	Hellhammer_091213_03 - Designation Run Report		
1/3/2014	AUGS Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence		
2/4/2014	US8641597 US Patent DeLeval Surgical Procedure for the treatment of female urinary incontinence: tension-free inside-out transobturator urethral suspension		
	CV of Piet Hinoul		
	Stanford School of Medicine Publication - Incontinence - Medical Articles - About Us - Department of Urology - Stanford		
??/??/13	GYNECARE TVT ABBREVO - Mesh Placement Sheet for Patient Consult TVTA-357-10 CA File		
6/22/2006	Gadot, H EMEA Launch Strategy		
	J&J "Our Credo" We believe our first . . .		
7/20/2011	Letter Dr. David Challoner to Dr. Jeffrey E. Shuren re seven recommendations proposed by FDA		
	510(k) Submission and Communications for TVT Exact		
6/13/2006	T 213 om-01 Proposed Revision - Dirt in pulp - chart method		
	TVT-R spreadsheet		
6/29/2010	Total Petrochemicals Certificate 10D0649		
	510(k) Submission and Communications for TVT Secure		
	Copy of IFU__in_Use__Production_Chart		
3/8/1991	FDA Device Labeling Guidance #G91-1		
	Mesh Weight Chart		
9/9/2011	Industry submission FDA advisory - Safety and Effectiveness of Surgical Mesh for the Treatment of SUI		
	TVT-O IFU		
	TVT Blue mesh, laser cut:810041BL		
3/12/2004	Sunoco 2004 MSDS		

## DOCUMENTS

Date	Description	Bates - Begin	Bates - End
6/13/2006	Draft No. 2 Dirt in pulp - chart method (Proposed revision of T 213 om-01)		
2/2/2015	tvf lightweight Google search		
	510(k) Submission and Communications for TVT-O		
11/3/2009	United States Patent De Leval US7611454		
??/??/02	ASTM D 1388-96 - Standard Test Method for Stiffness of Fabrics		
12/2/2014	About Banque Carnegie Luxembourg - HL - Banque Carnegie Luxembourg		
	GYNECARE TVT ABBREVO® Continenence System _ Ethicon#!videos		
	Chart of Responsive Documents		
	Transvaginal Mesh Implants - Independent Review - IR/02		
	AUGS Resident Learning Objections		
1/4/2014	NHS Scotland Consultant Outcomes Publication		
	Trial Testimony of Piet Hinoul in Linda Gross Trial		
	European Patent Specification EP1542596B1		
08/??/15	Technical Report - Using routinely available health data to examine the provision of, and outcomes following surgery for SUI and POP in Scotland		
10/2/2014	Independent Review - Minutes of Meeting, Atlantic Quay, Glasgow		
02/??/06	OHTA Series 2006; Vol 6, No. 3 Midurethral Slings for Women with Stress Urinary Incontinence		
	Product Catalogue - Herniamesh		
5/15/2002	K020652 Permarket notification for herniamesh T-sling		
	Table 1a: International Agency Reviews of Transvaginal Mesh Safety		
1/27/2005	United States Patent Application Publication De Leval US20050021086 20050127		
	T-Sling with Biosorb Products Ordering Information		
	Perry v. Ethicon Trial Exhibit 10311		
8/25/2014	Independent Review - Minutes of Meeting, Atlantic Quay, Glasgow		
12/4/2008	2008 Marlex MSDS		
9/4/2000	German Patent No. DE10043396C1 20.06.2002 and Certified Translation of Patent		
7/25/2003	Patent CA2497158C Devices for surgical treatment of female urinary incontinence		

## DOCUMENTS

Date	Description	Bates - Begin	Bates - End
2/4/2014	United States Patent De Leval US8641597		
8/25/2014	Independent Review - Agenda		
	Chart of Responsive Documents		
	Terms of Reference: Independent Review of surgery using vaginal mesh IR/01		
	Table 1a: International Agency Reviews of Transvaginal Mesh Safety		
10/2/2014	Independent Review Agenda IR/10		
4/17/2007	United States Patent De Leval US7204802		
	Gynecare Professional Education Digital Library		
	Trial Testimony of Melvyn Anhalt, MD in the Linda Batiste Trial		
	Independent Review Minutes of Meeting, Atlantic Quay, Glasgow - IR/16		
8/29/2003	2003 Marlex MSDS		
7/25/2003	Patent WO2004019786A1 - Devices for surgical treatment of female urinary incontinence		
3/8/1991	FDA Device Labeling Guidance #G91-1 (Blue Book Memo)		
	2011 Marlex MSDS		
01/??/13	OHTAC Recommendation: Midurethral Slings for Women with Stress Urinary Incontinence		
	Transvaginal Mesh Implants Independent Review Agenda IR/14		
	Chart of slings and sling characteristics		
10/9/2007	2007 Marlex MSDS		
	Ethicon opening statement/slides in Lewis v. Ethicon and supporting materials		
3/1/1997	Medical Device Reporting for Manufacturers by Department of Health and Human Services, Public Health Services, FDA		
1/28/1998	Tension Free Vaginal Tape (TVT) System 510(k)		
??/??/13	IUGA Annual Meeting - Ad		
8/12/2009	United States Patent Application Publication De Leval US20090306459		
	Transvaginal Mesh Short Life Working Group Terms of Reference IR/07		
2/28/2001	Phillips Sumika 2001 Marlex MSDS		
2/16/2009	IUGA 2009 Ital Sponsorship Invoice - 34th Annual Meeting Como, Italy June 10-20, 2009		
11/1/2007	FDA Science and Mission at Risk -- Report from Subcommittee on Science and Technology		
11/3/2009	United States Patent De Leval US7611454		
1/28/2004	2004 Marlex MSDS Chevron Phillips		

## DOCUMENTS

Date	Description	Bates - Begin	Bates - End
2/23/2015	Transvaginal Mesh Implants Independent Review Meeting Minutes, Atlantic Quay, Glasgow - IR/23		
	Questions to Boards about current practice in the surgical treatment of stress urinary incontinence and pelvic organ prolapse in women - IR/05		
	US Patent 6,306,079 B1 Mesh Pubovaginal Sling - Arnaldo F. Trabucco		
8/26/2013	TVT Patient Brochure Index 8-26-13		
	MHRA - A summary of the evidence on the benefits and risks of vaginal mesh implants		
5/24/2013	IFU__in_Use__Production_Chart		
	Sunoco 2006 MSDS		
3/12/2004	Sunoco 2004 MSDS		
7/13/2011	FDA Public Health Notification		
3/30/2015	Transvaginal mesh implants Independent Review - Meeting Minutes, Atlantic Quay, Glasgow - IR/27		
10/2/2015	Interim Report - The Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women		
	Transvaginal mesh implants, Independent Review, Meeting Minutes, Atlantic Quay, Glasgow - IR/20		
8/29/1997	1997 Marlex MSDS		
1/22/2015	Transvaginal mesh implants, Independent Review, Meeting Minutes, Atlantic Quay, Glasgow - IR/2		
	Demonstrative Procedure and Scar formation video		
3/29/2000	Repliform 10K		
06/??/2007	Repliform Patient Guide MVU1770 1.5M 06/07-06/09		
07/??/2004	Repliform Brochure BVU2050 10M 0704-0706 Guided Tissue Regeneration		
01/??/2016	Repliform IFU Rev L		

## LITERATURE

Author	Description	Journal Citation
Abbott S, Unger CA	Abbott [2014] Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery	Am J obstet Gynecol 2013;210:163.e1-8
Abdel-Fattah M, Barrington JW, et al	Pelvicol pubovaginal sling versus tension-free vaginal tape for treatment of urodynamic stress incontinence: a prospective randomized three-year follow-up study	Eur Urol. 2004 Nov;46(5):629-35
Abdel-fattah M, et al	Primary and repeat surgical treatment for female pelvic organ prolapse and incontinence in parous women in the UK: a register linkage study	BMJ Open 2011; 1:e000206
Abdel-Fattah M, et al	Lower urinary tract injuries after transobturator tape insertion by different routes: a large retrospective study	GJOG 2006; 113: 1377-1381
Abdel-Fattah M, Familusi A, et al	A randomised prospective single-blinded study comparing inside-out versus outside-in transobturator tapes in the management of female stress urinary incontinence (E-TOT study): 3 years follow-up.	Neurourol Urodyn 2011;30:825-826.
Abdel-Fattah M, Ford JA, et al	Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: A Meta Analysis of Effectiveness and Complications.	European Urology ,60: 468-80,24-May-11
Abdel-Fattah M, Mostafa A, et al	Prospective randomised controlled trial of transobturator tapes in management of urodynamic stress incontinence in women: 3-year outcomes from the Evaluation of Transobturator Tapes study.	Eur Urol. 2012 Nov;62(5):843-51. doi: 10.1016/j.eururo.2012.04.021. Epub 2012 Apr 14.
Abdel-fattah M, Ramsay I, et al	Evaluation of transobturator tapes (E-TOT) study: randomised prospective single-blinded study comparing inside-out vs. outside-in transobturator tapes in management of urodynamic stress incontinence: short term outcomes.	Eur J Obstet Gynecol Reprod Biol. 2010 Mar;149(1):106-11. doi: 10.1016/j.ejogrb.2009.11.023. Epub 2009 Dec 24
Abdel-Fattah M, Ramsay I, et al	Randomised prospective single-blinded study comparing 'inside-out' versus 'outside-in' transobturator tapes in the management of urodynamic stress incontinence: 1-year outcomes from the E-TOT study.	BJOG,117:870-8 ,12-Apr-10
Abdel-Fattah M, Sivanesan K, et al	How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape procedure.	BJU Int. 2006 Sep;98(3):594-8.
Abdelnaser KH, et al	The use of polypropylene mesh as a transobturator sling for the treatment of female stress urinary incontinence (early experience with 40 cases)	Int Urogynecol J 2008; 19: 833-838

## LITERATURE

Author	Description	Journal Citation
Abdelwahab O, Shedid I, et al	Tension-free vaginal tape versus secure tension-free vaginal tape in treatment of female stress Urinary Incontinence <sup>2</sup>	Current Urology(2010) 4 (2): 93-98
Abed H, Rahn DD, et al	"Incidence and Management of Graft Erosion, Wound Granulation, and Dyspareunia Following Vaginal Prolapse Repair with Graft Materials: A Systematic Review "	The International Urogynecology Journal,22:789-98,22-Mar-11
Abouassaly R, Steinberg JR, et al	Complications of tension-free vaginal tape surgery: a multi-institutional review.	BJU International,94:110-3 ,01-Jul-04
Abrams P et al	Synthetic Vaginal Tapes for Stress Incontinence: Proposals for Improved Regulation of New Devices in Europe	European Urology 60 (2011) 1207-1211
Abrams T	The Regulation of Prescription Drug Promotion	In Ethics and the Pharmaceutical Industry, 2005; 153-169
Achtari C, et al	Anatomical study of the obturator foramen and dorsal nerve of the clitoris and their relationship to minimally invasive slings	Int Urogynecol J (2006) 17: 330-334
ACOG	ACOG Committee Opinion 439 Informed Consent	ACOB 439 (2009)
ACOG	Patient Safety in Obstetrics and Gynecology	ACOG Committee opinion number 447, December 2009
Adile B, Granese R, Lo Bue A, et al	A prospective randomized study comparing laparoscopic Burch versus TVT: short and long term follow-up.	<a href="http://www.ics.org/Abstracts/Publish/41/000550.pdf">http://www.ics.org/Abstracts/Publish/41/000550.pdf</a>
Afonso JS, et a	Structural and thermal properties of polypropylene mesh used in treatment of stress urinary incontinence	Acta of Bioengineering and Biomechanics (2009) 11(3):
Agarwala N.	A randomized comparison of two synthetic mid-urethral tension-free slings.	UroToday Int J. 2008 Oct;1(4)
Agatstein EH, et al	The Raz Bladder Suspensions: Treatment of Stress Urinary Incontinence: 10 Years Personal Experience	The Open Urology & Nephrology Journal, 2014, 7, 86-90
Agnew G, Dwyer PL, et al	Functional outcomes following surgical management of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence	Int Urogynecol J (2014) 25:235-239
AGOS	Program of the 31st Annual Meeting of the American Gynecological and Obstetrical Society	AGOS 2012
Aigmuller, T.	Reason for dissatisfaction ten years after TVT procedure	Int Urogynecol J (2014) 25;213-217
Alajmo F, et al	Polypropylene suture fracture	Ann Thorac Surg 1985; 39(4):400
Alariqi SAS, et al	Biodegradation of γ-sterilised biomedical polyolefins under composting and fungal culture environments	Polym Degrad Stab 2006; 91:1105-1116
Albo ME, et al	Treatment success of retropubic and transobturator mid urethral slings at 24 months	J urology 2012 (188) 2281-2287
Albo ME, Richter HE, et al	Burch colposuspension versus fascial sling to reduce urinary stress incontinence	New England Journal of Medicine,356:2143-55,21-May-07

## LITERATURE

Author	Description	Journal Citation
Alcalay, Menachem	Burch colposuspension: a 10-20 year follow up	British Journal of Obstetrics and Gynaecology September 1995, Vol. 102, pp. 740-745
Aldrete V	Polypropylene Suture Fracture	Ann Thorac Surg 1984 Mar; 37(3):264
Alexander	Role of Suture Materials in the Development	Ann Surg 1967; 165(2): 192-199
Ali SAM, et al	Mechanisms of polymer degradation in implantable devices 1. Polycaprolactone	Biomater 1993; 14(9): 648-658
Ali, SAM, et al	The Mechanisms of Oxidative Degradation of Biomedical Polymers by Free Radicals	J App Polym Sci 1994; 51: 1389-1398
Ali, SAM, et al	Mechanisms of polymer degradation in implantable devices 2. Ply (DL-lactic acid)	J Biomed Mater Res 1992; 27:1409-1418
Alinsod R, et al	Initial outcomes of a stabilized adjustable minisling for female urinary stress incontinence	Abstract 865 (2009)
Al-Omary R, et al	Long term patient satisfaction after suburethral sling operation for stress incontinence	Abstract 381 Int Urogynecol J (2011) ss (Suppl 3): S1769-S2008
Altman AJ, et al	The breakdown of polypropylene in the human eye: is it significant?	Ann Ophthalmol 1986; 18:182-185
Altman D, Väyrynen T, et al	Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse.	New England Journal of Medicine, 364:1826-36, 5/12/2011
Altuna S, et al	Lower urinary tract injuries associated with the out-in transobturator tape: is cystoscopy required? An Argentinean multicenter experience	Int Urogynecol J (2007) 18 (Suppl I) S163-S164
Amaro, JL, et al	Clinical and quality-of-life outcomes after autologous fascial sling and tension-free vaginal tape: A prospective randomized trial	International Braz U Urol (2009) 35(1): 60-67
Amat I Tardiu L, Martínez et al	Contasure-Needleless compared with transobturator-TVT for the treatment of stress urinary incontinence.	Int Urogynecol J. 2011 Jul;22(7):827-33. doi: 10.1007/s00192-011-1380-9. Epub 2011 Mar 2.
Amid PK, et al	Biomaterials for abdominal wall hernia surgery and principles of their applications	Langenbecks Arch Chir 1994; 379:168-171
An YH, et al	Concise Review of Mechanisms of Bacterial Adhesion to Biomaterial Surfaces	J Biomed Mater Res Appl Biomater 1998; 43:338-348
Anderson JM	Biodegradation of polymers	Encyclopedia of Materials Science and Technology, Pergamon, London 2001: 560-563
Anderson, HA	Utilization of Adipose Tissue Biopsy in Characterizing Human Halogenated Hydrocarbon Exposure	Environ Health Perspect. 1985 May; 60:127-131
Anderson-Smiths C	Developing of the Pelvic Floor Disorder Registry	www.fda.gov
Andonian S, Chen T, et al	Randomized Clinical Trial Comparing Suprapubic Arch Sling (SPARC) and Tension-Free Vaginal Tape (TVT): One-Year Results	European Urology, 47:537-41, 13-Jan-05

## LITERATURE

Author	Description	Journal Citation
Andonian S, St-Denis B, et al	Prospective clinical trial comparing Obtape and DUPS to TVT: one-year safety and efficacy results.	Eur Urol. 2007 Jul;52(1):245-51. Epub 2007 Jan 10
Andrada Hamer M, Larsson PG, et al	One-year results of a prospective randomized, evaluator-blinded, multicenter study comparing TVT and TVT Secur.	Int Urogynecol J. 2013 Feb;24(2):223-9
Andrada Hamer M, Larsson PG, et al	Short-term Results of a Prospective Randomized Evaluator Blinded Multicenter Study Comparing TVT and TVT-Secur.	International Urogynecology Journal,22:781-787,16-Apr-11
Anger JT, Litwin MS, Wang Q, et al	Complications of sling surgery among female Medicare beneficiaries	Obstetrics & Gynecology,109:707-14,01-Mar-07
Anger JT, Weinberg AE, et al	Trends in surgical management of stress urinary incontinence among female Medicare beneficiaries	Urology,74:283-7,07-Jun-09
Angioli R, Plotti F, Muzii L, et al	"Tension-free vaginal tape versus transobturator suburethral tape: five-year follow-up results of a prospective, randomised trial"	European Urology 58 (2010) 671-677
Aniuliene R.	Tension-free vaginal tape versus tension-free vaginal tape obturator (inside-outside) in the surgical treatment of female stress urinary incontinence.	Medicina (Kaunas). 2009;45(8):639-43
Ansquer Y, et al	The suburethral sling for female stress urinary incontinence: a retropubic or obturator approach?	J Am Assoc Gynecol Laparosc 2004, 11(3):353-358
Anthanasiou S, Grigoriadis T, et al	Mixed Urodynamic Incontinence: TVT or TVT-O?	Int Urogynecol J (2009) 20 (Suppl 2): S73-S239
Apple DJ, Mamalis N, et al	Biocompatibility of implant materials: a review and scanning electron microscopic study	J Am Intraocul Implant Soc 1984 Winter; 10(1):53-66
Apte, et al	Pain after suburethral sling insertion for urinary stress incontinence	Pain Practice 2012; 12(2):88-110
Arco F., et al	TVT-O vs TVT a randomized trial in patients with different degrees of urinary stress incontinence.	Int Urogynecol J 2008; 19:917-926
Arunkalaivanan A, et al	Efficacy and safety of transobturator tape (Obtryx™) in women with stress urinary incontinence and intrinsic sphincter deficiency: results from international Obtryx™ registry	ICS 2009 Abst. 778
Arunkalaivanan AS and Barrington JW	Randomized trial of porcine dermal sling (Pelvicol implant) vs. tension-free vaginal tape (TVT) in the surgical treatment of stress incontinence: a questionnaire-based study	Int Urogynecology J (2003) 14: 17-23
Arutchevi J, et al	Biodegradation of polyethylene and polypropylene	Biotechnol 2008; 7:9-22
Asicioglu, O	A 5-year follow-up study comparing Burch colposuspension and transobturator tape for the surgical treatment of stress urinary incontinence.	Int J Gynecol Obstet.( 2014) April 125(1): 73-77
Aslanzadeh S, et al	Photodegradation of polypropylene thermal bonded non-woven fabric	Polym Degrad Stab 2005; 90:461-470

## LITERATURE

Author	Description	Journal Citation
Atassi Z, Reich A, Rudge A, et al	Haemorrhage and nerve damage as complications of TVT-O procedure: case report and literature review	Arch Gynecol Obstet 2008, 277:161-4
Athanasίου S, Grigoriadis T, et al	Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: Why do tapes fail?	Int Urogynecol J. 2013 Jul 27. [Epub ahead of print]
Atherton MJ and Stanton SL.	The tension-free vaginal tape reviewed: an evidence-based review from inception to current status.	BJOG,112:534-46, 5/1/2005
Atis G, Arisan S, Ozagari A, et al	Tissue reaction of the rat urinary bladder to synthetic mesh materials.	Scientific World Journal,9:1046-51,02-Oct-09
AUA	AUA Newsletter	13-Oct
AUA	Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update	
AUA	Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence	
AUGS	Corporate Members	<a href="http://www.augs.org/p/cm/ld/fid=24">http://www.augs.org/p/cm/ld/fid=24</a>
AUGS	Urinary Incontinence in Women	Practice Bulletin 155; November 2015
AUGS	Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders	
AUGS/SUFU	Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence	
Austoni E, et al	Partially absorbable tension-free sling (T-Sling/Uromesh 2) in non-invasive treatment of mild and severe anterior wall prolapse with stress urinary incontinence. Medium term follow up	Dept Urology, University of Milan, Italy
Avery DR	A cohort study to determine the outcome and complication rate and to classify complications using IUGA/ICS terminology following vaginal mesh for pelvic organ prolapse surgery	Int Urogynecol J (2012) 23 (Suppl 2):S43-S244
Azadi A, et al	Scanning electron microscopy (SEM) of vaginal mesh removed due to pelvic pain	Female Pelvic Med & Reconstr Surg 2013;19(5) S99 - Presentation Number: Poster 12
Azizi H, et al	Controlled-peroxide degradation of polypropylene: Rheological properties and prediction of MWD from rheological data	Polym Test 2008; 27:548-554
Bachman S, et al	An examination of spatial materials degradation of explanted polytetrafluoroethylene hernia meshes	Hernia 2009; 13(Suppl 1):S93
Baessler K, et al	Severe mesh complications following intravaginal slingplasty	Obstet Gynecol 2005; 106:713-6
Bai SW, Sohn WH, Chung DJ, et al	"Comparison of the efficacy of Burch colposuspension, pubovaginal sling, and tension-free vaginal tape for stress urinary incontinence"	Int J Gynaecol Obstet. 2005 Dec;91(3):246-51. Epub 2005 Oct 20

## LITERATURE

Author	Description	Journal Citation
Bako A, et al	Review of synthetic mesh-related complications in pelvic floor reconstructive surgery	Int Urogynecol J DOI 10.1007/s00192-008-0717-5
Ballard, J., et al	Harnessing a Health Information Exchange to Identify Surgical Device Adverse Events for Urogynecologic Mesh	Abstract
Banks CL, et al	Abscess formation following trans-obturator tape procedures	Int Urogynecol J (2006) 17 (Suppl 2):S171-S359 Abst 204
Barber M, et al	A multicenter randomized trial comparing the transobturator tape with tension-free vaginal tape for the surgical treatment of stress urinary incontinence	Abst 113
Barber MD, Brubaker L, et al	Defining success after surgery for pelvic organ prolapse.	Obstetrics and Gynecology,114:600-9,01-Sep-09
Barber MD, Kleeman S, et al	Transobturator tape compared with tension-free vaginal tape for the treatment of stress urinary incontinence: a randomized controlled trial.	Obstetrics & Gynecology,111:611-21,01-Mar-08
Barber MD.	"Cleveland Clinic leads multicenter trial of single-incision 'minisling' for stress urinary incontinence."	Ob/GYN & Women's Health Research Perspectives. Summer 2011. clevelandclinic.org/obgyn
Barber, M., et al	Single-Incision Mini-Sling Compared With Tension-Free Vaginal Tape for the treatment of Stress Urinary Incontinence	Obstetrics & Gynecology, Vol. 119, No. 2, Part 1 (Feb 2012)
Barber, MD, et al	Validation of the Surgical Pain Scales in Women undergoing Pelvic Reconstructive Surgery	Female Pelvic Med Reconstr Surg. 2012 ; 18(4): 198-204.
Barone WR, et al	The impact of boundary conditions on surface curvature of polypropylene mesh in response to uniaxial loading	J Biomechanics, Accepted 28 Feb 2015, In Press
Barone, DVM, MS, Mark A, et al	Determinants of Postoperative Outcomes of Female Genital Fistula Repair Surgery.	Obstet Gynecol, 2012 September; 120(3); 524-531, doi:10.1097/AOG.0b013e31826579e8.
Barry C, Lim YN, Muller R, et al	A multi-centre, randomised clinical control trial comparing the retropubic (RP) approach versus the transobturator approach (TO) for tension-free, suburethral sling treatment of urodynamic stress incontinence: the TORP study	The International Urogynecology Journal,19:171-8,19-Jul-07
Basok EK, Yildirim A, Atsu N, et al	Cadaveric fascia lata versus intravaginal slingplasty for the pubovaginal sling: surgical outcome, overall success and patient satisfaction rates.	Urol Int 2008;80(1):46-51
Basu M, et al	A randomised trial of a retropubic tension-free vaginal tape versus a mini-sling for stress incontinence	BJOG 2010; 117:730-735
Basu M, et al	Three-year results from a randomised trial of a retropubic mid- urethral sling versus the Miniarc single incision sling for stress urinary incontinence	Int Urogynecol J 2013

## LITERATURE

Author	Description	Journal Citation
Bazi, T	Letter to the Editor Re: Influence of TVT properties on outcomes of midurethral sling procedures: high-stiffness versus low-stiffness tape	Int Urogynecol J (2016) 27:1939-1940
Beets GL, et al	Foreign body reactions to monofilament and braided - Copy	Eur J Surg 1996; 162:823-825
Bekelman JE, et al	Scope and Impact of Financial Conflicts of Interest in Biomedical Research A Systematic Review	JAMA, January 22/29, 2003 Vol 289 No. 4, 454-465
Bellón JM, et al	In vitro interaction of bacteria with polypropylene/ePTFE prostheses	Biomater 2001; 22:2021-2024
Bemelmans BLH, Chapple CR.	Are slings now the gold standard treatment for the management of female urinary stress incontinence and if so which technique?	Curr Opin Urol 2003;13:301-307
Bendavid R Iakovlev V, et al	Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain2	Int J Clinical Med (2014)(5) 799-810
Beranová M, et al	Degradation of polyethylene exposed in mouse-liver homogenates by oxidation	Inter Biodeterior 1990; 27:297-304
Bernstein R, et al	Radiation -- oxidation mechanisms: Volatile organic degradation products from polypropylene having selective C-13 labeling studied by GC/MS	Polym Degrad Stab 2008; 93:854-870
Bertin D, et al	Polypropylene degradation: Theoretical and experimental investigations	Polym Degrad and Stab 2010; 95:782-791
Bertini F, et al	Characterization and thermal degradation of polypropylene -- montmorillonite nanocomposites	Polym Degrad Stab 2006; 91: 600-605
Bezerra CA and Bruschini H.	Suburethral sling operations for urinary incontinence in women.	Cochrane Database Syst Rev.
Bianchi-Ferraro AM, Jarmy-Di et al	Single-incision sling compared with transobturator sling for treating stress urinary incontinence: a randomized controlled trial.	Int Urogynecol J. 2013 24: 1459-1465
Bidmead J, et al	Sling techniques in the treatment of genuine stress incontinence	BJOG 2000,107(2): 147-156
Binnebosel M, et al.	Biocompatibility of prosthetic meshes in abdominal surgery	Semin Immunopathol. 2011; [Deleted Object]:235-243
Birolini C, Minossi JG, et al	Mesh Cancer: Long-Term Mesh Infection Leading to Squamous-Cell Carcinoma of the Abdominal Wall	Hernia,19-Apr-13
Blaivas J, Purohit R, et al	Salvage Surgery after Failed Treatment of Synthetic Mesh Sling Complications	J Urology, 2013 Oct, Vol 190, 1281-1286
Blaivas JG and Chaikin DC.	Pubovaginal fascial sling for the treatment of all types of stress urinary incontinence: surgical technique and long-term outcome.	The Urologic Clinics of North America,38:7-15,00-Jan-00
Blaivas JG, et al	Safety considerations for synthetic sling surgery	Nat. Rev. Urol. advance online publication 18 August 2015; doi:10.1038/nrurol.2015.183

## LITERATURE

Author	Description	Journal Citation
Blandon, R.E., Gebhart, J.B., et al	(2009). Complications from vaginally placed mesh in pelvic reconstructive surgery.	Int. Urogynecol J Pelvic Floor Dysfunct, 20(5), 523-531. doi: 10/1007/s00192-009-0818-9.
Blitstein J, et al	A noval composite sling for the treatment of stress urinary incontinence: first clinical experience	Presented June 22, 2001, Milan, Italy, XXIII International Congress of the European Hernia Society
Blomsted B, et al	Suture material and bacterial transport. An experimental study	Acta Chir Scand 1977; 143(2):71-3 abstract
Bodelsson G, et al	Short term complications of the tension free vaginal tape operation for stress urinary incontinence in women	BJOG (2002) 109: 566-569
Bonnet P, Waltregny D, et al	Transobturator vaginal tape inside out for the surgical treatment of female stress urinary incontinence: Anatomical considerations	The Journal of Urology,173:1223-8,01-Apr-05
Bouillot JL, et al	Parietal mesh abscess as an original presentation of cancer of the caecum	Digestive Surgery (1999) 16(2) 158-160
Bowler S	Preparing articles for publication in peer-reviewed journals	American College of Preventive Medicine www.acpm.org
Boyles SH, et al	Complications associated with transobturator sling.	Int Urogynecol J (2007) 18:19-22
Bracco P, et al	Comparison of polypropylene and polyethylene terephthalate (Dacron) meshes for abdominal wall hernia repair: A chemical and morphological study	Hernia 2005; 9:51-55
Brill Al.	The hoopla over mesh: what it means for practice.	Obstet Gynecol News,47:14-5 ,01-Jan-12
Brown BN, et al	Characterization of the host inflammatory response following implantation of prolapse mesh in rhesus macaque	Am J Obstet Gynecol 2015 Aug 7 doi 10.1016 [Epub ahead of print]
Brubaker L	Devices and meshes for the surgical treatment of prolapse and incontinence	Clinical Obstet and Gynecol 2013; 56(2):219-220
Brubaker L,	5-Year Continence Rates, Satisfaction and Adverse Events of Burch Urethropexy and Fascial Sling Surgery for Urinary Incontinence	The Journal of Urology
Brubaker L, Cundiff GW, et al	Abdominal sacrocolpopexy with Burch colposuspension to reduce urinary stress incontinence.	New England Journal of Medicine,354:1557-66,13-Apr-06
Brubaker L, et al	Adverse events over two years after retropubic or transobturator midurethral sling surgery findings from the Trial of Midurethral Slings (TOMUS) study	Am J Obstet Gynecol 2011; 205: 498.e1-6
Brubaker L, Maher C, et al	Surgery for pelvic organ prolapse.	Female Pelvic Medicine & Reconstructive Surgery,16:9-19,01-Jan-10
Brubaker L, Nygaard I, et al	Two-year outcomes after sacrocolpopexy with and without burch to prevent stress urinary incontinence.	Obstetrics and Gynecology,112:49-55, 7/1/2008

## LITERATURE

Author	Description	Journal Citation
Brubaker, et al	Adverse events over two years after retropubic or transobturator midurethral sling surgery: findings from the trial of midurethral sling (TOMUS) study	Am J Obstet Gynecol (2011); 205(5):498e1-498.e6
Brubaker, L.	(2006). Editorial: partner dyspareunia (hispareunia).	Int Urogynecol J Pelvic Floor Dysfunct, 17(4), 311. doi: 10.1007/s00192-006-0097-7
Brubaker, L., et al	Missing data frequency and correlates in two randomized surgical trials for urinary incontinence in women	Int Urogynecol J Published online 03/24/2015
Brubaker, L., et al.	A perfect storm.	Int Urogynecol J, 23(1), 3-4. doi: 10.1007/s00192-011-1596-8 (2012)
Bucknall	The choice of a suture to close abdominal incisions	Eur Surg Res 1983; 15(2):59-66 abstract
Buret A, et al	An in vivo model to study the pathobiology of infectious biofilms on biomaterials surfaces	J Biomed Mater Research 1991; 25: 865-874
Burns-Heffner, C., et al	Testing Compliance of Surgical Meshes Fabricated from Different Polymeric Biomaterials	Abstract #877 2014 Society for Biomaterials
Burton C, et al	Comments on Araco et al.: TVT-O vs TVT: a randomized trial in patients with different degrees of urinary stress incontinence	Int Urogynecol J 2009; 20:369
But I and Faganelj M.	Complications and short-term results of two different transobturator techniques for surgical treatment of women with urinary incontinence: a randomized study.	The International Urogynecology Journal,19:857-61,01-Jun-08
Cacciari I, et al	Isotactic polypropylene biodegradation by a microbial community: Physicochemical characterization of metabolites produced	Appl Environ Microbiol 1993; 59(11):3695-3700
Cadish L, Hacker M, et al	Characterization of Pain After Inside-Out Transobturator Midurethral Sling	Female Pelvic & Reconstructive Surgery Vol 20, (2) March/April 2014
Calhoun TR, Kitten DM	Polypropylene suture -- Is it safe?	J Vasc Surg 1986; 4:98-100
Calvo JJ, Alfara AH, et al	"Stress urinary incontinence surgery with MiniArc sling system: Our experience."	Actas Urológicas Españolas 2010;34(4):372-377
Cameron AP, et al	The treatment of female stress urinary incontinence: an evidenced-based review	Open Access J Urology 2011;3 109-120
Campagna L, et al	Transobturator (TO) T-sling (herniamesh) for the treatment of stress urinary incontinence: 3 years follow up study	IUGA Abstract 445
Campeau L, Tu LM, Lemieux MC, et al	A Multicenter, Prospective Randomized Clinical Trial Comparing Tension-Free Vaginal Tape Surgery and No Treatment for the Management of Stress Urinary Incontinence in Elderly Women	Neurourology and Urodynamics 26:990-994 (2007)

## LITERATURE

Author	Description	Journal Citation
Cao J., et al	In Vitro Study: Synthetic Prosthetic Meshes for Inguinal Hernia Repair	Presented at AATCC International Conference May 18-20 in Atlanta, GA AATCC Review November/December 2011
Capobianco G, Dessole M, et al	TVT-Abbrevio: efficacy and two years follow-up for the treatment of stress urinary incontinence	Clin Exp Obstet Gynecol (2014); 41(4): 445-447
Caquant, F., et al.	Safety of Trans Vaginal Mesh procedure: retrospective study of 684 patients.	J Obstet Gynaecol Res. 2008; 34(4):449-456
Carey M, Higgs P, Goh J, et al	Vaginal repair with mesh versus colporrhaphy for prolapse: a randomised controlled trial.	BJOG,116:1380-6,07-Jul-09
Carey M, Slack M, et al	Vaginal surgery for pelvic organ prolapse using mesh and a vaginal support device	BJOG 2008; 115:391-397
Carr BJ, et al	Biologic response to orthopedic sutures: A histologic study in a rabbit model	Orthopedics 2009; 32(11):828
Caruso S, Rugolo S, et al	Clitoral Blood Flow Changes After Surgery for Stress Urinary Incontinence: Pilot Study on TVT Versus TOT Procedures	Urology 70: 554-557, 2007
Casiano ER, et al	Does concomitant prolapse repair at the time of midurethral sling affect recurrent rates of incontinence	Int Urogynecol J (2011) 22:819-825
Cattoni,Elena; Serati M, et al	ISU Abs 5 Can preoperative overactive bladder (OAB) symptoms influence TVT-O outcome?	Neurolurol and Urodyn; International Society of Urology Conference abstracts 2012
Cayan, R.	Sexual function after surgery for stress urinary incontinence: vaginal sling versus Burch colposuspension.	Gynecol Obstet. 2008 Jan; 277(1):31-6 Epub 2007 Jul 25.
Celebi I, et al	Results of the tension-free vaginal tape procedure for treatment of female stress urinary incontinence: a 5-year follow-up study.	Arch Gynecol Obstet (2009) 279: 463-467
Cervigni M, Natale F, et al	Surgical Correction of Stress Urinary Incontinence Associated with Pelvic Organ Prolapse: Trans-Obturator Approach (Monarc) Versus Retropubic Approach (TVT)	Int Urogynecol J 2006;17(suppl. 2):S215 abstract 280. 31st annual IUGA meeting, Athens, Greece, 6-9 September 2006
Chae HD, Kim SR, Jeon GH, et al	A comparative study of outside-in and inside-out transobturator tape procedures for stress urinary incontinence.	Gynecol Obstet Invest. 2010;70(3):200-5. doi: 10.1159/000318866. Epub 2010 Jul 17.
Challoner, D, Korn, D	Medical Devices and the Public's Health The FDA 510(k) Clearance Process at 35 Years	Institute of Medicine of the National Academies Report Brief July 2011
Challoner, DR,	2011 - IOM Committee on the Public-Health Effectiveness of the FDA 510(k) Clearance Process - letter to FDA re 510k	IOM 2011
Challoner, DR, et al	Medical Devices and Health -- Creating a New Regulatory Framework for Moderate-Risk Devices	N Engl J Med 365:11: 977-979

## LITERATURE

Author	Description	Journal Citation
Chan JH, et al	Thermal Degradation kinetics of PP Part III. Thermogravimetric analyses	Polym Degrad Stab 1977; 57:135-149
Chapple C, Raz S, Brubaker L, et al	Mesh Sling in an Era of Uncertainty: Lessons Learned and the Way Forward	European Urology 64 (2013) 525-529
Charalambous S, Touloupidis S, et al	Transvaginal vs transobturator approach for synthetic sling placement in patients with stress urinary incontinence.	Int Urogynecol J Pelvic Floor Dysfunct. 2008 Mar;19(3):357-60. Epub 2007 Aug 29.
Chen X, Tong X, Jiang M, et al	A modified inexpensive transobturator vaginal tape inside-out procedure versus tension-free vaginal tape for the treatment of SUI: a prospective comparative study	Archives of Gynecology and Obstetrics,284:1461-6 ,22-Mar-11
Chen YH, Wang YJ, Li FP, and Wang	Efficacy and postoperative complication of tension-free vaginal tape-Secur for female stress urinary incontinence	Chinese Medical Journal,124:1296-9 ,01-May-11
Chen Z, Chen Y, Du GH, et al	Comparison of three kinds of mid-urethral slings for surgical treatment of female stress urinary incontinence	Urologia. 2010 Jan-Mar;77(1):37-41; discussion 42.
Chen, et al	A modified inexpensive transobturator vaginal tape inside-out procedure versus tension-free vaginal tape for the treatment of SUI: a prospective comparative study	Arch Gynecol Obstet (2011) 284:1461-1466
Chen, X., Li, H. et al.	An inexpensive modified transobturator vaginal tape inside-out procedure for the surgical treatment of female stress urinary incontinence.	Int Urogynecol J Pelvic Floor Dysfunct 20, 1365-8 (2009).
Chene G, Cotte B et al	Clinical and ultrasonographic correlations following three surgical anti-incontinence procedures (TOT, TVT and TVT-O)	Int Urogynecol J (2008) 19:1125-1131
Cheng D, Liu C.	Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five-year follow-up.	Eur J Obstet Gynecol Reprod Biol. 2012 Apr;161(2):228-31. doi: 10.1016/j.ejogrb.2012.01.011. Epub 2012 Feb 13.
Chinthakanan O, et al	Mesh removal following sling/mesh placement: a multicenter study	2014-A-1236-AUGS/IUGA
Chinthakanan O, et al	Indication and surgical treatment of midurethral sling complications: a multicenter study	2014-A-1239-AUGS/IUGS
Chinthakanan O, Miklos JR, et al	Indication and surgical treatment of midurethral sling complications	Int Urogynecol J (2014) 25 (Suppl 1):S144-S143
Chinthakanan O, Miklos JR, et al	Mesh Removal Following Sling/Mesh Placement: A Multicenter Study	Int Urogynecol J(2014)25(Suppl 1):S139-S140
Cho MK, Kim CH, Kang WD, et al	Comparison of the clinical and quality-of-life outcomes after the inside-out TVT-O procedure with or without concomitant transvaginal gynaecological surgery.	J Obstet Gynaecol. 2012 Apr;32(3):280-4. doi: 10.3109/01443615.2011.654290

## LITERATURE

Author	Description	Journal Citation
Choe JH, Kim JH, Na TG, et al	Comparative Study of Tension-Free Vaginal Tape (TVT) and Suprapubic Arc (SPARC) Sling Procedure for Female Stress Urinary Incontinence	International Urogynecology Journal 2005
Choi J, et al.	Use of Mesh During Ventral Hernia Repair in Clean-Contaminated and Contaminated Cases	Annals of Surgery, Vol 255, Number 1, Jan 2012
Cholhan HJ, et al	Pre-pubic approach to mid-urethral slings: 3-month interim report on peri-operative experience and complications	2007 Abstract
Cholhan HJ, Hutchings TB, et al	Dyspareunia associated with paraurethral banding in the transobturator sling	Am J Obstet Gynecol (2010);202:481.e1-5
Christensen LH, et al	Host tissue interaction, fate, and risks of degradable and nondegradable gel fillers	Dermatol Surg 2009; 35:1612-1619
Chrysostomou A	The management of stress urinary incontinence using transobturator tapes in a tertiary hospital in South Africa	Abst 0177 Oral presentations/Int J Gynecol & Obstet 10752 (2009) S93-S396
Chu CC	Textile-Based Biomaterials for Surgical Applications	Chapter 19 - Polymeric Biomaterials Second Ed, Revised and Expanded
Chu CC	The effect of gamma irradiation on the enzymatic degradation of polyglycolic acid absorbable sutures	J Biomed Mater Res 1983; 17:1029-1040
Chung C, Kingman T, Tsai L, et al	Serious Complications From a Single-Incision Midurethral Sling Placement	Obstet & Gynecol, February 2012, Vol 119, No. 2 Part 2, 464-466
CIR Expert Panel	Final report on the safety assessment of polyethylene	Int J Toxicol 2007; 26(Suppl. 1):115-127
Claassen J	The gold standard: not a golden standard	BMJ 2005; 330: 1121
Clarke, EGC, et al	Discussion on metals and synthetic materials in relation to tissues	Proceedings of the Royal Society of Medicine-London 1954; 46(8): 641-652
Clavè A, et al	Polypropylene as a reinforcement in pelvic surgery is not inert: Comparative analysis of 100 explants	Int Urogynecol J 2010; 21:261-270
Clayman HM	Polypropylene	Ophthalmol 1981; 88:959-964
Clifton MM, et al	Transvaginal sling excision: tips and tricks	Int Urogynecol J 2017; 28:155
Cobb WS, et al	The argument for lightweight polypropylene mesh in hernia repair	Surg Innov 2005 12: 63-69
Cobb, W., et al.	The Argument for Lightweight Polypropylene Mesh in Hernia Repair	Surgical Innovation 2005, 12(1):T1-T7
Coda A, et al	In vivo tissue reaction to different prosthetic materials in abdominal wall hernia repair	Hernia 2000; 4:206-211
Coda A, et al	Structural alterations of prosthetic meshes in humans	Hernia 2003; 7:29-34
Colin X, et al	Strategy for studying thermal oxidation of organic matrix composites	Compos Sci Technol 2005; 65:411-419

## LITERATURE

Author	Description	Journal Citation
Collinet P, Ciofu C, et al	Safety of inside-out transobturator approach for urinary stress incontinence treatment: prospective multicentric study of 994 patients - French TVT-O registry	Int Urogynecol J (2008) 19:711-715
Colombo M, Vitabello D, et al	Randomized study to compare pereyra and TVT procedures for women with stress urinary incontinence and advanced urogenital prolapse	International Urogynecology Journal August 2005, Volume 16, Issue 2 Supplement, pp S35-S130
Comiter CV	Complications of Female Incontinence Surgery	Chapter 19
CommonHealth	Surgery Under Scrutiny: What Went Wrong With Vaginal Mesh	<a href="http://commonhealth.wbur.org/2011/11">http://commonhealth.wbur.org/2011/11</a>
Conning DM, et al	Toxicity of polypropylene in tissue culture	Fd Cosmet Toxicol 1969; 7:461-472
Constantini E, Lazzeri M, Kocjanci	ICS Abs 3 Prolonged follow-up shows continence deterioration after transobturator tape: Results from a randomised controlled trial.	International Continence Society Mtg 2013
Contemporary OB/GYN Staff	American Urogynecologic Society voices opposition to restrictions on transvaginal mesh	Contemporary OB/GYN May 01, 2013
Cornel G	Fracture of Polypropylene Suture	Ann Thorac Surg 1982; [Deleted Object]:641
Cornelis R, Hogewoning C, et al	The introduction of mid-urethral slings: an evaluation of literature (Update)	Int Urogynecol J (2015) 26: 229-234
Cornelis R, Hogewoning C, et al	The introduction of mid-urethral slings: an evaluation of literature	Int Urogynecol J (Published online 21 August 2014))
Cornu J-N, Haab F.	Mini-slings for female stress urinary incontinence: Not yet at the age of reason.	Eur Urol 2011;60:481-483
Cornu, JN, et al	Midterm prospective evaluation of TVT-Secur reveals high failure rate	European Urology 58 (2010) 157-161
Corona, R., et al	Tension-free Vaginal Tapes and Pelvic Nerve Neuropathy	J Min Invas Gynecol 2008; 15(3):262-267
Corporate Action Network	Putting Women at Risk, The Case Against Pelvic Mesh Report	Corporate Action Network August 2014
Corton M	Critical anatomic concepts for safe surgical mesh	Clin Obstet Gynecol 2013 Jun; 56(2):247-56
Coskun B, Zimmers PE, et al	Minislings can cause complications	Int Urogynecol J (2015) 26:557-562
Cosson M, et al	Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material?	Int Urogynecol J (2003) 14: 169-178
Costa L, et al	In vivo UHMWPE biodegradation of retrieved prosthesis	Biomater 1998; 19: 1371-1385
Costa L, et al	Oxidation of orthopaedic UHMWPE	Biomater 2002; 23:1613-1624
Costa L, et al	Analysis of products diffused into UHMWPE prosthetic components in vivo	Biomater 2011; 22:307-315

## LITERATURE

Author	Description	Journal Citation
Costa P	Comparisons of Safety and Efficacy of the Obtryx Sling and Advantage Mid-Urethral Sling for the Treatment of Stress Urinary Incontinence: Propensity Matching Results in a Large International Registry	Abstract 614 (2010)
Costa P, Ballanger P, et al	Transobturator Tape for SUI. Preliminary Results of Prospective Multicenter Register	ICS Abstract #379,05-Oct-03
Costa P, Grise P, et al	Surgical treatment of female stress urinary incontinence with a trans-obturator-tape (T.O.T.) Uratape: short term results of a prospective multicentric study	European Urology
Costello CR, et al	Materials Characterization of Explanted Polypropylene Hernia Meshes	J Biomed Mater Res Part B: Appl Biomater 2007; 83B:44-49
Costello K, et al	Investigation of the mechanical strength of explanted polypropylene hernia meshes (abstract)	Poster presented at 12th annual meeting of Institute of Biological Engineering, St. Louis, MO March 29-April 1, 2007
Costello, CR, et al	Characterization of heavyweight and lightweight polypropylene mesh explants from a single patient	Surg Innov 2007;14(3):168-176
Coughlin RW, et al	Surface roughness enhances upward migration of bacteria on polymer fibers above liquid cultures	J Biomater Sci Polym Edn 1999; 10(8):827-844
Cox A, Herschorn S, et al	Surgical management of female SUI: Is there a gold standard?	Nat Rev Urol 2013;10:78-89
Cozad MJ, et al	Materials characterization of explanted polypropylene, polyethylene terephthalate, and expanded polytetrafluoroethylene composites: Spectral and thermal analysis	J Biomed Mater Res Part B: Appl Biomater 2010; 94B:455-462
Cozad MJ, et al	Patient Factor Correlation of Explanted Composite Hernia Mesh Material properties	Presented at the Society of Biomaterials, April 2010, Seattle, WA
Crivellaro S, et al	Transvaginal sling using acellular human dermal allograft: safety and efficacy in 253 patients	J Urol 2004; 172: 1374-1378
Crosby E, Abernethy M, et al	Symptom Resolution After Operative Management of Complications From Transvaginal Mesh	Obstet & Gynecol January 2012, Vol 123, No. 1, 134-139
Cundiff GW, Varner E, et al	Risk factors for mesh/suture erosion following sacral colpopexy.	The American Journal of Obstetrics & Gynecology,199:688.e1-5,31-Oct-08
Curfman, GD., et al	Medical Devices -- Balancing Regulation and Innovation	N Engl J Med 365; 11: 975-977
Czerny J	Thermo-oxidative and photo-oxidative aging of polypropylene under simultaneous tensile stress	J App Polym Sci 1972; 16:2623-2632
Daher N, et al	Pre-pubic TVT: an alternative to classic TVT in selected patients with urinary stress incontinence	European J Obstet & Gynecol and Reproduct Biology 107 (2003) 205-207

## LITERATURE

Author	Description	Journal Citation
Daly JO	Vaginal mesh products: each an entity unto itself	BJOG 2015: DOI: 10.1111/1471-0528.13534
Daneshgari F, Kong W, et al	Complications of Mid Urethral Slings: Important Outcomes for Future Clinical Trials.	The Journal of Urology Vol 180, 1890-1897 November 2008.
Darai E, Frobert JL, et al	Functional results after the suburethral sling procedure for urinary stress incontinence: a prospective randomized multicentre study comparing the retropubic and transobturator routes.	Eur Urol 2007 Mar;51(3):795-801; discussion 801-2. Epub 2006 Sep 8
Das, N., et al	Review Article: Microbial Degradation of Petroleum Hydrocarbon Contaminants: An Overview	Biotechnology Res Int 2011: 1-13 Article ID 941810
Dati S, Cappello S, et al	Single-incision minsling (AJUST®) vs Obturator Tension-free vaginal shortened tape (TVT-Abbrevio™) in surgical management of female stress urinary incontinence	Dati poster XX FIGO World Congress of Gynecology and Obstetrics Rome, 7-12 October 2012
Dati S, et al	Obtryn (TM) system: transobturator out-in sling in the treatment of isolated or pop-associated urinary incontinence (Abstract only)	Int Urogynecol J (2007) 18 (Suppl I): S152
Dati S, Rombola P, et al	Single-Incision Minisling (Ajust) vs Obturator Tension-Free Vaginal Shortened Tape (TVT-Abbrevio) in Surgical Management of Female Stress Urinary Incontinence	Poster presentations/ Int J Gynecol & Obstet 119S3 (2012) S670
David-Montefiore E, et al	Peri-operative complications and pain after the suburethral sling procedure for urinary stress incontinence: a French prospective randomised multicentre study comparing the retropubic and transobturator routes.	European Urology,49:133-8 ,02-Nov-05
de Carvalho CL, et al	A study of the controlled degradation of polypropylene containing pro-oxidant agents	SpringerPlus 2.1 (2013): 623
de Leval J, Thomas A, and Waltregn	The original versus a modified inside-out transobturator procedure: 1-year results of a prospective randomized trial	The International Urogynecology Journal,22:145-56,21-Sep-10
de Leval J.	Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator Vaginal Tape Inside-Out	European Urology,44:724-30,02-Oct-03
de Oliveira LM, Girao MJBC, et al	Comparison of Retro-Pubic TVT, Pre-Pubic TVT and TVT Transobturator in Surgical Treatment of Women With Stress Urinary Incontinence	International Urogynecology Journal
De Ridder D, et al	Single incision mini-sling versus a transobutator sling: a comparative study on MiniArc and Monarc slings	Int Urogynecol J (2010) 21:773-778
De Souza A	Sexual function following retropubic TVT and transobturator Monarch sling in women with intrinsic sphincter deficiency: a multicentre prospective study .	Int Urogynecol J (2012) 23:153-158

## LITERATURE

Author	Description	Journal Citation
de Tayrac R, Deffieux X, et al	A prospective randomized trial comparing tension-free vaginal tape and transobturator suburethral tape for surgical treatment of stress urinary incontinence.	American Journal of Obstetrics and Gynecology,190:602-8 ,01-Mar-04
de Tayrac R, Deffieux X, et al	A transvaginal ultrasound study comparing transobturator tape and tension-free vaginal tape after surgical treatment of female stress urinary incontinence.	Int Urogynecol J (2006) 17: 466-471
de Tayrac R, Droupy S, et al	A Prospective Randomized Study Comparing TVT and Transobturator Suburethral Tape (TOT) for the Surgical Treatment of Stress Incontinence	ICS Abstract #344,,05-Oct-03
de Tayrac R, et al	Basic science and clinical aspects of mesh infection in pelvic floor reconstructive surgery	Int Urogynecol J 2011; 22:775-780
de Tayrac, R et al.	Long-term anatomical and functional assessment of trans-vaginal cystocele repair using a tension-free polypropylene mesh.	Int Urogynecol J (2006) 17: 483-488.
de Tayrac, R. & Letouzey, V.	Basic science and clinical aspects of mesh infection in pelvic floor reconstructive surgery.	Int Urogynecol J, 22(7), 775-780. doi: 10.1007/s00192-011-1405-4.
Debodinance P, et al	Tolerance of synthetic tissues in touch with vaginal scars: review to the point of 287 cases	Euro J Obstet & Gynecol and Reprod Biology 1999; 87: 23-30
Debodinance P, Legrange E, et al	TVT Secur: Prospective Study and Follow up to 1 Year about 150 Patients	International Urogynecology Journal,19(Supp. 1):211-S12 ,00-Jan-00
Debodinance P.	Trans-obturator urethral sling for surgical correction of female stress urinary incontinence: Outside-in (Monarc) versus inside-out (TVT-O). Are the two ways reassuring?	Eur J Obstet Gynecol Reprod Biol,133:232-8
Deffieux X, Daher N, et al	Transobturator TVT-O versus retropubic TVT: results of a multicenter randomized controlled trial at 24 months follow-up	Int Urogynecol J. 2010 Nov;21(11):1337-45.
Delorme E	Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women	Prog Urol 2001 Dec; 11(6):1306-13
Delorme E, Droupy S, et al	Transobturator tape (Uratape): a new minimally-invasive procedure to treat female urinary incontinence	European Urology,45:203-7 ,01-Feb-04
Demirkesen, O	Does vaginal anti-incontinence surgery affect sexual satisfaction? A comparison of TVT and Burch - colposuspension.	Int Braz J Urol. 2008 Mar- Apr; 34 (2):214-9
Demirkesen, O, et al	Are the effectiveness and complication rates of transoburator and tension-free vaginal tape similar?	Türk Üroloji Dergisi: 34(4): 456-462, 2008
Deng DY, et al	Presentation and Management of Major Complications of Midurethral Slings: Are Complications Under-reported?	Neurourology and Urodynamics 26:46-52 (2007)

## LITERATURE

Author	Description	Journal Citation
Deng M, Chen G, et al	A Study on In Vitro Degradation Behavior of a Poly(glycolide-co-L-lactide) Monofilament	Acta Biomaterialia,4:1382-91,11-Apr-08
Deng, DY, et al	Presentation and management of major complications of midurethral slings: are complications under-reported?	Neurourol and Urodyna (2007) 26: 46-52
Deprest, et al.	The need for preclinical research on pelvic floor reconstruction	BJOG 2013; 120: 141-143
Descazeaud A, Salet-Lizée, et al	Traitement de l'incontinence urinaire d'effort par bandelette TVT-O : résultats immédiats et à un an	Gynécologie Obstétrique & Fertilité
DeSouza R, Shapiro A, et al	"Adductor brevis myositis following transobturator tape procedure: a case report and review of the literature."	Int Urogyn J 2007;18:817-820
Detollenaere RJ, De Boon J, et al	Short term anatomical results of a randomized controlled non inferiority trial comparing sacrospinous hysteropexy and vaginal hysterectomy in treatment of uterine prolapse stage 2 or higher	Int Urogynecol J (2013) 24 (Suppl 1): S1-S152
Detollenaere, RJ., et al	Short Term Anatomical Results of a Randomized Controlled Non Inferiority Trial Comparing Sacrospinous Hysteropexy and Vaginal Hysterectomy in Treatment of Uterine Prolapse Stage 2 or Higher	Int Urogynecol J (2013) 24 (Suppl 1): S1-S152
Deval B and Haab F.	Management of the complications of the synthetic slings.	Current Opinion in Urology
Deval B, Birsan A, et al	Objective and Subjective Cure Rates After Tension-free Vaginal Tape for Treatment of Urinary Incontinence.	Urology,58: 702-706 ,01-Nov-01
Di Piazza L, Piroli Torelli D, et al	Complications in short suburethral sling positioning.	Int Urogyn J 2009;20(Suppl 3):S403-404 IUGA Abst 430
Diallo S, Cour F, et al	Evaluating single-incision slings in female stress urinary incontinence: The usefulness of the CONSORT statement criteria.	Urol 2012;80:535-541
Dietz HP, Vancaillie P, et al	Mechanical Properties of Urogynecologic Implant Materials	The International Urogynecology Journal,14:239-43; discussion 243,05-Aug-03
Dobson A, et al	Trans-obturator surgery for stress urinary incontinence: 1-year follow-up of a cohort of 52 women	Int Urogynecol J (2006) Accepted 6 March 2006
Dooley Y, et al	Urinary Incontinence Prevalence: Results From the National Health and Nutrition Examination Survey	J Urol 2008; 179: 656-661
Dougherty S, et al	Endogenous Factors Contributing to prosthetic device infections	Infect Dis Clin North Am 1989; 3(2):199-209
Drahoradova P,	Longitudinal trends with improvement in quality of life after TVT, TVT O and Burch colposuspension procedures.	Med Sci Monit. 2011; 17(2):CR67-72

## LITERATURE

Author	Description	Journal Citation
Drahoradova P, Masata J, et al	Comparative Development of Quality of Life Between TVT and Burch Colposuspension	Proceedings of the 34th Annual Meeting of the International Continence Society and the International Urogynecological Association August 25-27; Paris, France (, 2004) Abstract 278
Drews RC	Polypropylene in the human eye	Am Intra-Occular Implant Soc J 1983 Spring 9:137-142
Duckett J, Baranowski A	Pain after suburethral sling insertion for urinary stress incontinence	Int Urogynecol J (2013) 24:195-201
Duckett JR, Jain S	Groin pain after a tension-free vaginal tape or similar suburethral sling: management strategies	BJU Int. 2005 Jan;95(1):95-7
Duggan PF	Time to abolish "gold standard"	BMJ 1992; 304:1568-1569
DukeMedicine	Alert - Pelvic floor disorders Incontinence and vaginal prolapse	DukeMedicine
Dunn GE, et al	Changed Women: The Long-Term Impact of Vaginal Mesh Complications	Female Pelvic Med Reconstr Surg 2014;20: 131-136
Duong TH, Taylor D, et al	A Multicenter Study of Vesicovaginal Fistula Formation Following Cystotomy During Hysterectomy for Benign Indications	Felmale Pelvic Med & Reconstruc Surgery (2010)16(2) Supp S5-S43
Dwyer PL, et al	Synthetic mesh in pelvic reconstructive surgery: an ongoing saga	Int Urogynecol J (2016) 27:1287-1288
Dwyer, PL	Editorial The 75% rule: all stress incontinence procedures are alike	Int Urogynecol J (2011) 22:769-770
Dyrkorn OA, Kulseng-Hanssen et al	TVT compared with TVT-O and TOT: results from the Norwegian National Incontinence Registry.	Int Urogynecol J. 2010 Nov;21(11):1321-6. doi: 10.1007/s00192-010-1195-0. Epub 2010 Jun 18.
EAU	Guidelines on Surgical Treatment of Urinary Incontinence	Published online 6 November 2012
EAU 2009:	Single-incision mid-urethral sling has high cure rate for stress urinary incontinence.	Medscape Mar 31, 2009.
Eland IA, et al	Attitudinal surgery of voluntary reporting of adverse drug reactions	Br J Clin Pharmacol (1999) 48, 623-627
El-Barky E, El-Shazly A, et al	Tension free vaginal tape versus Burch colposuspension for treatment of stress urinary incontinence.	Int Urol Nephrol. 2005;37(2):277-81
Elgamasy AK, et al	The use of polypropylene mesh as a transobturator sling for the treatment of female stress urinary incontinence (early experience with 40 cases).	Int Urogynecol J Pelvic Floor Dysfunct. 2008 Jun;19(6):833-8.
El-Hefnawy AS, Wadie BS, et al	TOT for treatment of stress urinary incontinence: how should we assess its equivalence with TVT?	Int Urogynecol J. 2010 Aug;21(8):947-53
Elkadry EA, et al	Patient-selected goals: A new perspective on surgical outcome	Am J Obstet Gynecol 2003;189:1551-8.)

## LITERATURE

Author	Description	Journal Citation
Ellington DR and Richter HE.	Indications, Contraindications, and Complications of Mesh in Surgical Treatment of Pelvic Organ Prolapse	Clinical Obstetrics & Gynecology,56:276-88,01-Jun-13
Elliott CS, et al	Might pelvic surgeons be unaware of their surgical failures? Patient reporting and perceptions after failed incontinence or pelvic organ prolapse surgery	Female Pelvic Med Reconstr Surg. 2015 Sep-Oct;21(5):298-300
Elser, D	New Options for Stress Urinary Incontinence	The Female Patient, Supp. Aug. 2009
ElSheemy MS, et al	Use of surgeon-tailored polypropylene mesh as a needle-less single-incision sling for treating female stress urinary incontinence: Preliminary results	Arab Journal of Urology (2015) xxx, xxx-xxx Article in press
Elzevier, Henk Willem	Female Sexual Function after Surgery for Stress Urinary Incontinence: Transobturator Suburethral Tape vs. Tension-Free Vaginal Tape Obturator	J Sex Med 2008; 5: 400-406
Endo M, et al	Mesh contraction: in vivo documentation of changes in apparent surface area utilizing meshes visible on magnetic resonance imaging in the rabbit abdominal wall model	Int Urogynecol J (2014) 25:737-743
Engelsman AF, et al	The phenomenon of infection with abdominal wall reconstruction	Biomater 2007; 28:2314-2327
English E, et al	Assessing the use of the IUGA/ICS classification system for prosthesis/graft complications in publications from 2011 to 2015	Urogynecol J 2016; 27:1905. doi:10.1007/s00192-016-3056-y
Enzelsberger H, Schalupny J, et al	TVT versus TOT - A prospective randomized study for the treatment of female stress urinary incontinence at a followup of 1 year [German].	Geburtsh Frauenheilk 65:506-511
Ethicon, iNC. 2012	Sacrocolpopexy with ARTISYN™ Y-Shaped Mesh, Sales Process	ETH.MESH.08114911 - ETH.MESH.08114934
Falconer, C., et al	Influence of Different Sling Materials on Connective Tissue Metabolism in Stress Urinary Incontinent Women	Int Urogynecol J (2001) (Suppl 2): S19-S23
Fan, B, et al	A new surgery for recurrent or persist stress urinary incontinence in females after primary mid-urethral slings	Int J Clin Exp Med 2014;7(1):122-128
Farrell SA,	The evaluation of stress incontinence prior to primary surgery	J obstet Gynaecol Can 2003;25(4):313-8
Fayolle B, et al	Oxidation induced embrittlement in polypropylene - a tensile testing study	Polym Degrad Stab 2000; 70:333-340
Fayolle B, et al	Initial steps and embrittlement in the thermal oxidation of stabilized polypropylene films	Polym Degrad Stab 2002; 75:123-129
Fayolle B, et al	Macroscopic heterogeneity in stabilized polypropylene thermal oxidation	Polym Degrad Stab 202; 77:515-522

## LITERATURE

Author	Description	Journal Citation
FDA	FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence	20-Oct-08
FDA	§801.63 Medical devices; warning statements for devices containing or manufactured with chlorofluorocarbons and other class I ozone-depleting substances	2014 Food and Drug Administration, HHS §801.63
FDA	510(k) Summary Caldera Medical Inc. T-Sling K0505165	Caladera Medical, Inc.
FDA	510(k) Premarket Notification K050516 T-Sling Herniamesh S.R.L.	FDA
FDA	Surgical mesh for treatment of women with pelvic organ prolapse and stress urinary incontinence	FDA Executive Summary 2011
FDA	FDA's Role and Activities	FDA webpage 4/29/2014
FDA	801.63 Medical devices; warning statements for devices containing or manufactured with chlorofluorocarbons and other class I ozone-depleting substances; Subpart D-Exemptions from Adequate Directions for Use	Food and Drug Administration 21 CFR Ch. I (4-1-14 Edition)
Feifer A and Corcos J.	The use of synthetic sub-urethral slings in the treatment of female stress urinary incontinence.	Int Urogynecol J (2007) 18:1087-1095
Feiner B and Maher C.	Vaginal mesh contraction: definition, clinical presentation, and management.	Obstetrics & Gynecology, 115:325-30, 01-Feb-10
Feng CL, Chin HY, Wang KH.	Transobturator vaginal tape inside out procedure for stress urinary incontinence: results of 102 patients.	Int Urogynecol J Pelvic Floor Dysfunct. 2008 Oct;19(10):1423-7. doi: 10.1007/s00192-008-0658-z. Epub 2008 May 31.
Feola A, Moalli PA, et al	Stress-Shielding the impact of Mesh Stiffness on Vaginal Function	Female Pelvic Med Reconstr. Surgery (2011) 17(5): S54-S110
Feola, A.	Deterioration in biomechanical properties of the vagina following implantation of a high-stiffness prolapse mesh	BJOG An International Journal of Obstetrics and Gynaecology 2013
Fianu, S, et al	Absorbable polyglactin mesh for retropubic sling operations in female urinary stress incontinence	Gynecol Obstet Invest 1983; 16:45-50
Firoozi F and Goldman HB.	Pure transvaginal excision of mesh erosion involving the bladder	The International Urogynecology Journal,, 04-Apr-13
Fischer A, Fink T, et al	Comparison of retropubic and outside-in transoburator sling systems for the cure of female genuine stress urinary incontinence	European Urology, 48:799-804, 15-Aug-05
Flam F, Boijsen M, and Lind F.	Necrotizing fasciitis following transobturator tape treated by extensive surgery and hyperbaric oxygen.	Int Urogynecol J (2009) 20:113-115

## LITERATURE

Author	Description	Journal Citation
Flemming, HC	Relevance of biofilms for the biodeterioration of surfaces of polymeric materials	Polym Degrad Stab 1998; 59:309-315
Fletcher AP	Spontaneous adverse drug reaction reporting vs event monitoring: a comparison	J Royal Society Med (1991) 84: 341-344
Flock F, Reich A, et al	Hemorrhagic complications associated with tension-free vaginal tape procedure.	Obstetrics & Gynecology,104:989-994,01-Nov-04
Flood CG, et al	Anterior colporrhaphy reinforced with Marlex mesh for the treatment of cystoceles	Int Urogynecol J Pelvic Floor Dysfunct 1998; 9(4): 200-4
Food and Drug Administration (FDA).	FDA Safety Communication: Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse.	13-Jul-11
Food and Drug Administration (FDA).	FDA executive summary. Surgical mesh for the treatment of women with pelvic organ prolapse and stress urinary incontinence.	Obstetrics and Gynecology Devices Advisory Committee Meeting,, 9/8/2011
Foote J, et al	Referral Patterns and Complications of Midurethral Slings	Abstract 843
Ford, AA, Rogerson L, et al	Mid-urethral sling operations for stress urinary incontinence in women (Review)	The Cochran Collaboration, The Cochran Library 2015, Issue 7
Frautschi JR, et al	Degradation of polyurethanes in vitro and in vivo comparison of different models	Colloids Surf B Biointerfaces 1993; 1:305-313
Freeman R, Holmes D, et al	What patients think: patient-reported outcomes of retropubic versus trans-obturator mid-urethral slings for urodynamic stress incontinence - a multi-centre randomised controlled trial	Int Urogynecol J. 2011 Mar;22(3):279-86
Frenkl TL, Rackley RR, et al	Management of Iatrogenic Foreign Bodies of the Bladder and Urethra Following Pelvic Floor Surgery	Neuro and Urodynam (2008)27:491-495
Frostling H, et al	Analytical, occupational and toxicologic aspects of the degradation products of polypropylene plastics	Scand J Work Environ Health 1984; 10:163-169
Funk MJ, Siddiqui NY, et al	Long-term Outcomes After Stress Urinary Incontinence Surgery	Obstetrics & Gynecology,120:83-90,01-Jul-12
Gallo J, et al	The relationship of polyethylene wear to particle size distribution and number: A possible factor explaining the risk of osteolysis after hip arthroplasty	J Biomed Mater Res Part B: Appl Biomater 2010; 94B:171-177
Gamble T, et al	Predicting persistent detrusor overactivity after sling procedures	Int Urogynecol J (2008) 19 (Suppl 1): S64-S65
GAO	Medical Devices FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process	GAO Report to Congressional Addressees January 2009
Garber, AM	Modernizing Device Regulation	N Engl J Med (2010) 362:13: 1161-1163
Garcia-Urena, M.A., et al	Differences in polypropylene shrinkage depending on mesh position in an experimental study.	Am J Surg, 193(4), 538-542. doi: 10.1016/j.amjsurg.2006.06.045

## LITERATURE

Author	Description	Journal Citation
Gebhart JB, Dixon DA, et al	Three-year outcomes of Uretex Urethral Support System for treatment of stress urinary incontinence	The International Urogynecology Journal,19:1075-9,28-Feb-08
Genesis Medical	CL Médical I-STOP brochure and reference publications	
Geoffrion R, et al	Closing the Chapter on Obtape: a case report of delayed thigh abscess and a literature review	J Obstet Gynaecol Can 2008; 30(2): 143-147
Gerstenbluth, RE., et al	Simultaneous Urethral Erosion of Tension-Free Vaginal Tape and Woven Polyester Pubovaginal Sling	J Urol. 2003, Aug; 170 (2 Pt 1): 525-6
Ghoniem G, et al	Evaluation and outcome measures in the treatment of female urinary stress incontinence: International Urogynecological Association (IUGA) guidelines for research and clinical practice	Int Urogynecol J (2008) 19:5-33
Ghoniem G, et al	Evaluation and outcome measures in the treatment of female urinary stress incontinence: International Urogynecological Association (IUGA) guidelines for research and clinical practice	Int Urogynecol J (2008) 19:5-33
Giarenis I, et al	Management of recurrent stress urinary incontinence after failed midurethral sling: a survey of members of the International Urogynecological Association (IUGA)	Int Urogynecol J 2015; 26(9):1285-1291
Gilberti C, et al	Transobturator Tape for Treatment of Female Stress Urinary Incontinence: Objective and Subjective Results After a Mean Follow-up of Two Years.	Urology 2007;69:703-707
Gillera JP, et al	An evidence-based approach to the evaluation and management of stress incontinence in women	Curr Opin Urol 2005; 15:236-243
Goldstein HS	Selecting the right mesh	Hernia 1999;3:23-26
Gomelsky A, et al	Biocompatibility Assessment of synthetic sling materials for female stress urinary incontinence	J Uro (2007)178:1171-1181
Goodman SB, et al	Quantitative comparison of the histological effects of particulate polymethylmethacrylate versus polyethylene in the rabbit tibia	Arth Orthop Trauma Surg 1991; 100:123-126
Goodman, SB	The histological effects of the implantation of different sizes of polyethylene particles in the rabbit tibia	J Biomed Mater Res 1990; 24:517-524
Göpferich A	Mechanisms of polymer degradation and erosion	Biomater 1995; 17:105-114
Grant DN, et al	Conjugation of gold nanoparticles to polypropylene mesh for enhanced biocompatibility	J Mater Sci: Mater Med 2011; 22:2803-2812
Grant DN, et al	Degradation Mechanism of Human Explanted Heavy Weight Polypropylene Hernia Meshes	Presented at the Society for Biomaterials, April 2010, Seattle, WA
Grant S, et al	Hernia meshes: new answers to an old problem	University of Missouri - Engineering 2010

## LITERATURE

Author	Description	Journal Citation
Greca FH, et al	The influence of differing pore sizes on the biocompatibility of two polypropylene meshes in the repair of abdominal defects	Hernia 2001; 5:59-64
Green J, Buencamino D, et al	A comparison of the transobturator tape and transabdominal tension free vaginal tape procedures for the surgical treatment of stress urinary incontinence	Presented at the 35th Annual Meeting of the International Continence Society, 28th August-2nd September 2005, Montreal, Canada.
Green TR, et al	Polyethylene particles of a critical size are necessary for the induction of cytokines by macrophages in vitro	Biomater 1998; 19:2297-2302
Greenwald D, et al	Mechanical comparison of 10 suture materials before and after in Vivo incubation	J Surg Res 1994; 56(4):372-377
Gristina AG	Biomaterial-centered infection - microbial adhesion versus tissue integration	Science 1987; 237(4822):1588-1595
Groutz A, Cohen A, et al	The safety and efficacy of the ""inside-out"" trans-obturator TVT in elderly versus younger stress-incontinent women: a prospective study of 353 consecutive patients.	Neurourol Urodyn. 2011 Mar;30(3):380-3. doi: 10.1002/nau.20976.
Groutz A, Levin I, Gold R, et al	""Inside-out"" transobturator tension-free vaginal tape for management of occult stress urinary incontinence in women undergoing pelvic organ prolapse repair."	Urology. 2010 Dec;76(6):1358-61. doi: 10.1016/j.urology.2010.04.070. Epub 2010 Oct 25.
Groutz A, Rosen G, Gold R, et al	Long-term outcome of transobturator tension-free vaginal tape: efficacy and risk factors for surgical failure.	J Womens Health (Larchmt). 2011 Oct;20(10):1525-8. doi: 10.1089/jwh.2011.2854. Epub 2011 Aug 5.
Gryta J, et al	The influence of polypropylene degradation on the membrane wettability during membrane distillation	J Membrane Sci 2009; 326:493-502
Guelcher SA, et al	Oxidative degradation of polypropylene pelvic mesh in vitro	Int Urogynecol J (2015) 26 (Suppl 1):S55-S56
Guerrero KL, Emery SJ, et al	"A randomised controlled trial comparing TVT, Pelvicol and autologous fascial slings for the treatment of stress urinary incontinence in women "	BJOG 2010 Nov;117(12):1493-502.
Guidoin R, Chakfe N	Aneurysmal Deterioration of Arterial Substitutes	Current Therapy in Vascular Surgery 2: 324-328
Gutierrez G, et al	Thermal oxidation of clay-nanoreinforced polypropylene	Polym Degrad Stab 2010; 95:1708-1715
Haferkamp, A., et al	Urethral Erosion of Tension-Free Vaginal Tape	J Urol. 2002;167(1): 250
Hammad FT, et al	Erosions and Urinary Retention Following Polypropylene Synthetic Sling: Australasian Surgery	Eur Urol 47 (2005) 641-647

## LITERATURE

Author	Description	Journal Citation
Hammett J, et al	Short-term surgical outcomes and characteristics of patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery	Int Urogynecol J (2014) 25:465-470
Han WHC.	Burch colposuspension or tension-free vaginal tape for female urinary incontinence? (Abstract).	International Urogynecology Journal and Pelvic Floor Dysfunction
Handa VL, et al	Banked human fascia lata for the suburethral sling procedure: a preliminary report	Obstet Gynecol 88(6): 1045-9 1996 Dec
Hansen BL, et al	Long-Term Follow-up of Treatment for Synthetic Mesh Complications	Female Pelvic Med Reconstr Surg 2014;20: 126-130
Harding CK, et al	A prospective study of surgeon and patient-perceived outcome following transobturator tape insertion for treatment of urodynamic stress incontinence	Br J Med and Surg Urol (2009) 2, 197-201
Hartung DM, et al	Reporting Discrepancies between clinicaltrials.gov results database and peer-reviewed publications	Ann Intern Med 2014;160:477-483
Hassan MF, et al	Treatment success of transobturator tape compared with tension free vaginal tape for stress urinary incontinence at 24 months: a randomized controlled trial	Open J Obstet and Gynecol, 2014, 4, 169-175
Haylen, BT, et al	An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor	Neurourology and Urodynamics,30:2-12,01-Jan-11
Hazell L, et al	Under-reporting of adverse drug reactions a systematic review	Drug Safety 2006; 29(5) 385-396
Hazewinkel MH, Hinoul P, et al	Persistent groin pain following a trans-obturator sling procedure for stress urinary incontinence: a diagnostic and therapeutic challenge	The International Urogynecology Journal,20:363-5,04-Sep-08
Health Canada	Health Canada Warns of Serious, Life-Altering Complications Associated with Transvaginal Mesh - NewsInferno	<a href="http://www.newsinferno.com/health-canada-warns">http://www.newsinferno.com/health-canada-warns</a>
Heinonen, P.	Tension-free vaginal tape procedure without preoperative urodynamic examination: Long-term outcome	International Journal of Urology (2012) 19, 1003-1009
Heise, CP, et al	Mesh Inguinodynia: A New Clinical Syndrome After Inguinal Herniorrhaphy?	J Am Coll Surg. 1998 Nov; 187(5): 514-8
Heniford, B.T.	""The benefits of lightweight meshes in Ventral Hernia Repair in Ventral Hernia Repair""	Video produced by Ethicon. 2007
Hernández-Gascón B, et al	Mechanical behaviour of synthetic surgical meshes: Finite element simulation of the herniated abdominal wall	Acta Biomaterialia 7 (2011) 3905-3913
Herniamesh	MEDICA - Germany November 16-19 Publication	Herniamesh

## LITERATURE

Author	Description	Journal Citation
Herniamesh	Female urinary incontinence and vaginal vault suspension: T-Sling® PP	Herniamesh publication
Herniamesh	T-Sling® plus for female urinary incontinence through Single Vaginal Incision	Herniamesh publication
Hilton P	Commentary: Trials of surgery for stress incontinence -- thoughts on the 'Humpty Dumpty principle'	BJOG 2002;109:1081-1088
Hilton P	Long-term follow-up studies in pelvic floor dysfunction: the Holy Grail or a realistic aim?	BJOG 2008; 115: 135-143
Hilton, P., et al	Postural Perineal Pain Associated With Perforation of the Lower Urinary Tract Due to Insertion of a Tension-Free Vaginal Tape	BJOG (2003) 110: 79-82
Hines, Jonas Zajac, et al.	Left to Their Own Devices: Breakdowns in United States Medical Device Premarket Review	PLOS Med 7(7): e1000280 July 13, 2010
Hinoul P, Bonnet P, Krofta L, et al	An anatomic comparison of the original versus a modified inside-out transobturator procedure	Int.Urogynecol J(2011) 22(8) 997-1004
Hinoul P, et al	Anatomical variability in the trajectory of the inside-out transobturator vaginal tape technique (TVT-O)	Int Urogynecol J (2007) 18:1201-1206
Hinoul P, et al	TVT obturator system versus TVT secur: a randomized controlled trial, short term results	Int Urogynecol J (2009) 20:S213
Hinoul P, et al	A Randomized, Controlled Trial Comparing an Innovative Single Incision Sling With an Established Transobturator Sling to Treat Female Stress Urinary Incontinence	J Urology 2011 (185): 1356-1362
Hinoul P, Roovers JP, et al	Surgical management of urinary stress incontinence in women: A historical and clinical overview.	Eur J Obstet Gyn Reprod Biol 2009;145:219-225
Hogewoning CR, et al	Erratum to: The introduction of mid-urethral slings: an evaluation of literature	Int Urogynecol J 2015;26:1403-1404
Hogston P	Single surgeon experience with 125 trans-obturator sling procedures	Int Urogynecol J (2011) 22 (Suppl 3) S1947
Hohenfellner R, et al	Sling Procedures	Chapter 7 - S. L. Stanton et al., Surgery of Female Incontinence © Springer-Verlag Berlin Heidelberg 1986
Hokenstad ED, et al	Health-related quality of life and outcomes after surgical treatment of complications from vaginally placed mesh	Female Pelvic Med Reconstr Surg 2015;21: 176-180
Holmgren, C	Quality of life after tension-free vaginal tape surgery for female stress incontinence	Scandinavian Journal of Urology and Nephrology, 2006; 40: 131-137
Hong MK, Liao CY, et al	Internal Pudendal Artery Injury during Prolapse Surgery Using Nonanchored Mesh	J Min Invas Gynecol (2011) 18, 678-681

## LITERATURE

Author	Description	Journal Citation
Hota LS, Hanaway K, et al	TVT-Secur (Hammock) Versus TVT-Obturator: A Randomized Trial of Suburethral Sling Operative Procedures.	Female Pelvic Reconstructive Surgery,18:41-45,01-Jan-12
Hou JC, et al	Outcome of Transvaginal Mesh and Tape Removed for Pain Only	The Journal of Urology Vol 192, 856-860, September 2014
Houwert RM, Renes-Zijl C, et al	TVT-O versus Monarc after a 2-4-year follow-up: a prospective comparative study.	Int Urogynecol J Pelvic Floor Dysfunct. 2009 Nov;20(11):1327-33. doi: 10.1007/s00192-009-0943-5. Epub 2009 Jul 14.
Howden NS, Zyczynski HM, et al	Comparison of autologous rectus fascia and cadaveric fascia in pubovaginal sling continence outcomes	The American Journal of Obstetrics & Gynecology,194:1444-9,31-Mar-06
Hsiao SM, et al	Sequential comparisons of postoperative urodynamic changes between retropubic and transobturator midurethral tape procedures	World J Urol 2008 Dec;26(6):643-8
Hubka P, Masata J, Nanka O, et al	Possible complications of the TVT-S vaginal tape in the H-position.	ICS Abstract #286,,00-Jan-00
Hubka P, Nanka O, Martan A, et al	Anatomical study of position of the TVT-O to the obturator nerve influenced by the position of the legs during the procedure: based upon findings at formalin-embalmed and fresh-frozen bodies.	Archives of Gynecology and Obstetrics
Hurtado EA, Appell RA	Management of complications arising from transvaginal mesh kit procedures: a tertiary referral center's experience	Int Urogynecol J (2009) 20:11-17
Iakovlev V	Explanted surgical meshes: what pathologists and industry failed to do for 50 years	Virchows Arch (2014) 465 (Suppl 1):S1-S379
Iakovlev V, et al	Pathological findings of transvaginal polypropylene slings explanted for late complications: Mesh is not inert	ICS Abstract 228
Iakovlev V, et al	Pathological findings of transvaginal polypropylene slings explanted for late complications: mesh is not inert	IUGA Abstract 228 (2010)
Iakovlev V, et al	Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients	J Biomed Mater Res Part B 2015:00B:000-000.
Iakovlev V, Guelcher S, et al	In vivo degradation of surgical polypropylene meshes: A finding overlooked for decades	Virchows Arch (2014) 465 (Suppl 1): S35
Iakovlev VV, Carey ET, Steege J	Pathology of Explanted Transvaginal Meshes	Accepted Abstract
Iakovlev VV, et al	Pathology of Explanted Transvaginal Meshes	Int J Med Health Pharmaceu and Biomedical Engineering 2014, (8)9: 510-513
Iakovlev, V.,	PS-24-006 Explanted surgical meshes: what pathologists and industry failed to do for 50 years	Virchows Arch (2014) 465 (Suppl 1): S337

## LITERATURE

Author	Description	Journal Citation
Iakovlev, V., et al	OFP-13-001 In vivo degradation of surgical polypropylene meshes: A finding overlooked for decades	Virchows Arch (2014) 465 (Suppl 1): S35
Iakovlev V, et al	A Pathology of Mesh and Time Dysejaculation, Sexual Pain, and Orchialgia Resulting From Polypropylene Mesh Erosion Into the Spermatic Cord	Ann Surg. 2017 Jan 6. doi: 10.1097/SLA.0000000000002134. [Epub ahead of print]
ICS	ICS Fact Sheets A Background to Urinary and Fecal Incontinence Prepared by the Publications & Communications Committee	13-Jul
Iglesia CB	Pelvic Organ Prolapse Surgery: Long-term Outcomes and Implications for Shared Decision Making	The Journal of American Medical Association,309:2045-6,15-May-13
Iglesia CB, et al	The use of mesh in gynecologic surgery	Int Urogynecol J (1997)8:105-115
Iglesia CB, Sokol AI, et al	Vaginal mesh for prolapsed: a randomized controlled trial.	Obstetrics & Gynecology,116:293-303,01-Aug-10
Iglesia, CB	Stop Using Synthetic Mesh for Routine Repair of Pelvic Organ Prolapse Start Performing Native Tissue Repairs and Reserve Mesh for Selective Cases	OBG Management 2013; 25: 24-25
Ignjatovic I, et al	Transobturator tension-free composite sling for urethral support in patients with stress urinary incontinence: Favorable experience after 1 year follow up	Inter J Urol 2006; 13: 728-732
Imel A, et al	In Vivo Oxidative Degradation of Polypropylene Pelvic Mesh	Biomaterials (2015), doi: 10.1016/j.biomaterials.2015.09.015.
Irwin BH, et al	Robotic-Assisted Laparoscopic Partial Nephrectomy	Chapter 4, New Technologies in Urology, John Lumley Series Editor
ISO	International Standard ISO10993-13 Identification and quantification of degradation products from polymeric medical devices	ISO10993-13
Isom-Batz G and Zimmern PE	Vaginal mesh for incontinence and/or prolapse: caution required:	Expert Rev Med Devices 2007; 4(5): 675-679
IUGA	2005 IUGA Grafts Roundtable International Urogynecological Association: The Usage of Grafts in Pelvic Reconstructive Surgery Symposium 2005 July 8-10, 2005, Lago Mar Resort, Fort Lauderdale FL, USA	Int Urogynecol J (2006) 17: S1-S3
IUGA	Stress Urinary Incontinence A Guide for Women	IUGA 2011

## LITERATURE

Author	Description	Journal Citation
Jaburek L, Jaburkova J, et al	Risk of haemorrhagic complications of retropubic surgery in females: anatomic remarks	Biomedical Papers of the Medical Faculty of the University Palacky, Olomouc, Czech Republic,155:75-7,01-Mar-11
Jacquetin, B., et al	Complications of Vaginal Mesh: Our Experience	Int Urogyn J 2009; 20:893-6
Jallah Z, et al	The impact of prolapse mesh on vaginal smooth muscle structure and function	BJOG 2015; DOI: 10.1111/1471-0528.13514.
Jarman-Smith ML, et al	Porcine collagen crosslinking, degradation and its capability for fibroblast adhesion and proliferation	J Mater Sci Mater Med 2004;15:925-932
Jelovsek JE, Barber MD, et al	Randomised trial of laparoscopic Burch colposuspension versus tension-free vaginal tape: long-term follow up	BJOG,115:219-25; discussion 225,01-Jan-08
Jha, Swati	Impact of Incontinence Surgery on Sexual Function: A Systematic Review and Meta-Analysis	J Sex Med 2012; 9: 34-43
Jones, Keisha, Beola A, et al	Tensile Properties of Commonly Used Prolapse Meshes	Int Urogynecol J Pelvic Floor Dysfunct (2009); 20(7); 847-853
Jongebloed WL, et al	Degradation of polypropylene in the human eye: A sem-study	Doc Ophthalmol 1986; 64:143-152
Jonsson Funk M, Siddiqui NY, et al	Sling revision/removal for mesh erosion and urinary retention: long-term risk and predictors	Am J Obstet Gynecol 2013; 208:73.e1-7
Jordan DR, et al	The use of vicryl mesh in 200 porous orbital implants	Reprinted from Ophthalmic Plastic & Reconstructive Surgery 2003; 19(1)
Juang CM, Yu KJ, Chou P, et al	Efficacy analysis of trans-obturator tension-free vaginal tape (TVT-O) plus modified Ingelman-Sundberg procedure versus TVT-O alone in the treatment of mixed urinary incontinence: a randomized study	European Urology,51:1671-8,16-Jan-07
Julia JJ, et al	Long term experience in 72 patients with the Advantage® sling system	www.bostonscientific.com/gynecology
Julian TM.	The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall.	The American Journal of Obstetrics and Gynecology,175:1472-5,01-Dec-96
Juma S and Brito CG.	Transobturator tape (TOT): Two years follow-up	Neurourol.Urodynam. (2007) 26:37-41
Jung HC, Kim JY, Lim HS, et al.	Three-year Outcomes of the IRIS procedure for Treatment of Female Stress Urinary Incontinence: Comparison with TVT Procedure.	J Korean Med Sci. (2007); 22: 497-501.
Junge K, et al	Elasticity of the anterior abdominal wall and impact for reparation of incisional hernias using mesh implants	Hernia 2001; 5:113-118
Junge, K., Rosch, R. Klinge, U.et a	Risk factors related to recurrence in inguinal hernia repair: a retrospective analysis.	Hernia (2006)10: 309-315.

## LITERATURE

Author	Description	Journal Citation
Kaelin-Gambirasio I, Jacob S, et al	Complications associated with transobturator sling procedures: analysis of 233 consecutive cases with a 27 months follow-up.	BMC Womens Health. 2009 Sep 25;9:28. doi: 10.1186/1472-6874-9-28.
Kane AR, et al	Midurethral Slings for Stress Urinary Incontinence	Clinical Obstetrics and Gynecol (2008) 51(1): 124-134
Kang D, et al	Abdominovaginal technique for complete removal of transobturator slings	Presentation
Kang D., et al	MP75-16 Patient Quality of Life After Removal of Vaginal Mesh	Urology J Vol 191, No. 4S e879
Kapoor R, et al	Is modified Raz technique of midurethral sling a reliable and cost effective method of treating stress urinary incontinence?	Indian J Urol. 2011 JanMar 27(1): 34-38.
Karaca E, et al	Analysis of the fracture morphology of polyamide, polyester, polypropylene, and silk sutures before and after implantation in vivo	J Biomed Mater Res Part B: Appl Biomater 2008; 87B:580-589
Karateke A, Haliloglu B, Cam C, et al	Comparison of TVT and TVT-O in Patients with Stress Urinary Incontinence: Short-term Cure Rates and Factors Influencing the Outcome. A Prospective Randomised Study.	Australian and New Zealand Journal of Obstetrics and Gynaecology 2009; 49:99-105
Karram MM, Segal JL, et al	Complications and untoward effects of the tension-free vaginal tape procedure.	Obstetrics and Gynecology, 101:929-32. ,01-May-03
Karsenty G, et al	Severe soft tissue infection of the thigh after vaginal erosion of transobturator tape for stress urinary incontinence	Int Urogynecol J 2007;18:207- 221
Katz S, et al	Bacterial adherence to surgical sutures a possible factor in suture induced infection	Ann Surg 1981; 194(1):35-41
Kausch HH	The effect of degradation and stabilization on the mechanical properties of polymers using polypropylene blends as the main example	Macromol Symp 2005; 225:165-178
Kavvadias T, Klinge U, Schuessler	"Ch. 56 Alloplastic Implants for the Treatment of Stress Urinary Incontinence"	Hernia Repair Sequelae , editors, V. Schumpelick, RJ Fitzgibbons, Springer-Verlag publ, 2010, pp. 439-444
Kennelly MJ, et al	Prospective evaluation of a single incision sling for stress urinary incontinence	J Urology (2010)184: 604-609
Kenton K, et al	Surgical treatment for stress urinary incontinence	ACOG 48th Annual Clinical Meeting, San Francisco, CA May 2000
Kenton K, et al	Open Burch urethropexy has a low rate of perioperative complications	Am J Obstet Gynecol 2002;187:107-110.
Kenton K, et al	Multiple foreign body erosions after laparoscopic colposuspension with mesh	Am J Obstet Gynecol 2002;187:252-3.
Kenton K, et al	Research education in obstetrics and gynecology: how are we doing?	Am J Obstet Gynecol 2007;197:532.e1-532.e4.

## LITERATURE

Author	Description	Journal Citation
Kenton K, et al	How well are we training residents in female pelvic medicine and reconstructive surgery?	Am J Obstet Gynecol 2008;198:567.e1-567.e4.
Kenton K, et al	The global burden of female pelvic floor disorders	BJU International 2006; 98 Supp 1, 1-5
Kenton K, et al	Pelvic Floor Symptoms Improve Similarly After Pessary and Behavioral Treatment for Stress Incontinence	Female Pelvic Med Reconstr Surg. 2012 ; 18(2): 118-121.
Kenton K, et al	5-year longitudinal follow-up after retropubic and transobturator midurethral slings	J Urol 2013;193(1):203-210
Kenton KS, et al	Uncomplicated erosion of polytetrafluoroethylene grafts into the rectum	Obstet Gynecol 2002;187:233-4.
Kessler, DA	Introducing MEDWatch A New Approach to Reporting Medication and Device Adverse Effects and Product Problems	JAMA (1993) 269 (21): 2765-2768
Khandwala S, Lucent V, et al	Preliminary Results of Peri-Operative and 3-Month Outcomes From a World-Wide Observational Registry of Tension-Free Vaginal Tapes in Women with Stress Urinary Incontinence	ICS Abstract 493
Khanuengkitkong S, et al	Delayed vaginal and urethral mesh exposure: 10 years after TVT surgery	Int Urogynecol J (2013) 24: 519-521
Kim J, Na Y, Lee J, Seo J. et al.	Comparative Study of Tension-free Vaginal Tape (TVT) and Suprapubic arc (SPARC) Sling Procedure for Female Stress Urinary Incontinence.	V. Schumpelick, RJ Fitzgibbons, Springer-Verlag publ, 2010, pp. 439-444
Kim JY, Jung HC, Moon KH, et al	Comparisons of IRIS, TVT and SPARC Procedure for Stress Urinary Incontinence.	European Urology Supplement
King RN, et al	Polymers in contact with the body	Environ Health Perspect 1975; 11:71-74
Kjohde, Preben	Prognostic factors and long-term results of the Burch colposuspension	Acta Obstet Gynecol Scand 1994; 73: 642-64
Kjohde, Preben	Long-term efficacy of Burch colposuspension: a 14 year follow-up study	Acta Obstet Gynecol Scand 2005: 84:767-772
Klein-Patel M, et al	Ultra-lightweight synthetic mesh has similar cellular response but increased tissue ingrowth relative to heavier weight prototype	Female Pelvic Med Reconstr. Surgery (2011) 17(5): S54-S110
Klinge U et al	Shrinkage of Polypropylene Mesh in vivo An Experimental Study in Dogs	Eur J Surg 1998; 164:965-969
Klinge U, et al	High structural stability of textile implants prevents pore collapse and preserves effective porosity at strain	BioMed Research Internal (2015) Art ID 953209; 1-7
Klinge U, et al	Do Multifilament Alloplastic Meshes Increase the Infection	J Biomed Mater Res Appl Biomater 2002; 63:765-771
Klinge U, Klosterhalfen B, et al	Foreign Body Reaction to Meshes Used for the Repair of Abdominal Wall Hernias	Eur J Surg 1999; 165: 665-673
Klinge, U., et al	Shrinking of Polypropylene Mesh In Vivo: An Experimental Study in Dogs	Eur J Surg. 1998: 164; 965-969

## LITERATURE

Author	Description	Journal Citation
Klinge, U., et al	Do Multifilament Alloplastic Meshes Increase the Infection Rate? Analysis of the Polymeric Surface, the Bacteria Adherence, and the In Vivo Consequences in a Rat Model	J Biomed Mater Res 2002; 63:765-771
Klosterhalfen	Pathology of traditional surgical nets for hernia repair after long-term implantation in humans	Chirurg 2000; 71: 43-51
Klosterhalfen B and Klinge U.	The lightweight and large porous mesh concept for hernia repair	Expert Rev. Med. Devices, 2005; 2(1)
Kobashi KC	Management of Erosion of Graft Materials in Pelvic Floor Reconstruction	The Scientific World J (2009) 9, 32-26
Kobashi, K, et al	Erosion of Woven Polyester Pubovaginal Sling	The Journal of Urology, Vol. 162, 2070-72 (Dec 1999)
Kobashi, K, et al	Management of Vaginal Erosion of Polypropylene Mesh Slings	The Journal of Urology, Vol. 169, 2242-2243 (June 2003)
Koch, YKP, et al	Long-term results of the acellular human dermal allograft sling with transvaginal bone anchors	J Pelvic Med Surg 2006;12:317-323
Kociszewski J	Tape Functionality: Sonographic Tape Characteristics and Outcome After TVT Incontinence Surgery	Neurourol Urodynam. 27.6 (2008): 485-490
Koelbl H, Halaska M,et al	Burch Colposuspension and TVT: Perioperative Results of a Prospective Randomized Trial in Patients with Genuine Stress Incontinence.	Neurourol Urodyn 22 (2003): 327.
Kondo A, Isobe Y, Kimura K, et al	Efficacy, Safety and Hospital Costs of Tension-free Vaginal Tape and Pubovaginal Sling in the Surgical Treatment of Stress Incontinence.	J Obstet Gynaecol Res. 2006 Dec;32(6):539-44.
Koops, S, et al	What determines a successful tension-free vaginal tape? A prospective multicenter cohort study: Results from The Netherlands TVT database	Am J Obstet Gynecol (2006) 194. 65-74
Krause H, et al	Biomechanical properties of raw meshes used in pelvic floor reconstruction	Int Urogynecol J (2008) 19: 1677-1681
Krauth JS, Rasoamiamanana H,et al	Sub-urethral tape treatment of female urinary incontinence--morbidity assessment of the trans-obturator route and a new tape (I-STOP): a multi-centre experiment involving 604 cases	European Urology
Krofta L, et al	TVT and TVT-O for Surgical Treatment of Primary Stress Urinary Incontinence Prospective Randomized Trial.	Int Urogynecol J 2010;21:141-148
Krofta L, Feyereisl J, et al	"TVT-S for Surgical Treatment of SUI: Prospective Trial, 1-Year follow-up"	Int Urogynecol J (2010)21:779-85,
Kuhn, A.	Sexual function after suburethral sling removal for dyspareunia	Surg Endosc (2009) 23:765-768
Kuo HC.	Comparison of video urodynamic results after the pubovaginal sling procedure using rectus fascia and polypropylene mesh for stress urinary incontinence	The Journal of Urology,65:163-8,01-Jan-01

## LITERATURE

Author	Description	Journal Citation
Kuuva N and Nilsson CG.	A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure	Acta Obstetrica et Gynecologica Scandinavica ,81:72-7,01-Jan-02
Kuuva, N, et al.	Long-term results of the tension-free vaginal tape operation in an unselected group of 129 stress incontinent women	Acta Obstetrica Gynecologica Scandanavica 2006(85: 4 482-87)
Kwon SY, Latchamsetty KC, et al	Inflammatory Myofibroblastic Tumor of the Urinary Tract Following a TVT	Female Pelvic Medicine & Reconstructive Surgery,18:249-51,01-Jul-12
Labrie J, van der Graaf Y,et al	Protocol for physiotherapy OR TVT Randomised efficacy trial (PORTRET): a multicenter randomized controlled trial to assess the cost-effectiveness of the tension free vaginal tape versus pelvic floor muscle training in women with symptomatic moderate to severe stress urinary incontinence	BMC Women's Health 2009;9:24-32
Lapitan MC, Cody JD, and et al	Open retropubic colposuspension for urinary incontinence in women.	Cochrane Database of Systematic Reviews ,CD002912,21-Jan-09
Latthe PM, Foon R, and Tooze-Hobso	Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications	BJOG 2007; 114:522-531
Latthe PM, Singh P, Foon R, et al	Two routes of transobturator tape procedures in stress urinary incontinence: a meta-analysis with direct and indirect comparison of randomized trials.	BJUI 2009; 106:68-76
Laurikainen E, et al	Retropubic TVT Compared with Transobturator TVT (TVT-O) in Treatment of Stress Urinary Incontinence Five-year Results of a Randomized Trial.	Öbstet Gynecol 2007;109:4-11
Laurikainen E, Valpas A, et al	Retropubic compared with transobturator tape placement in treatment of urinary incontinence: a randomized controlled trial	Obstetrics & Gynecology
Lee D, Bacsu C, et al	Meshology: a fast-growing field involving mesh and/or tape removal procedures and their outcomes	Expert Rev. Med Devices Early online 1-16 (2014)
Lee D, Dillon B, Lemack G, et al	"Transvaginal Mesh Kits-- How ""Serious"" Are the Complications and Are They Reversible?"	Urology 81: 43-49, 2013
Lee KS, Choo MS, Lee YS, et al	Prospective comparison of the 'inside-out' and 'outside-in' transobturator-tape procedures for the treatment of female stress urinary incontinence	Int Urogynecol J. (2008) 19:577-582.
Lee KS, Han DH, Choi YS, et al	A prospective trial comparing tension-free vaginal tape and transobturator vaginal tape inside-out for the surgical treatment of female stress urinary incontinence: 1-year follow up.	J Urology (2007) 177: 214-218

## LITERATURE

Author	Description	Journal Citation
Lemer ML, et al	The use of artificial material in sling surgery	Chapter 41 - The Urinary Spiniter 2001
Lensen EJM, et al	Comparison of two trocar-guided trans-vaginal mesh systems for repair of pelvic organ prolapse: a retrospective cohort study	Int Urogynecol J 2013; 24: 1723-1731
Levin I, Groutz A, Gold R, et al	Surgical Complications and Medium-term Outcome Results of Tension-free Vaginal Tape: A Prospective Study of 313 Consecutive Patients.	Neurology and Urodynamics ,23:7-9,01-Jan-04
Levy, B., et al	Best Options, Techniques, and Coding Tips for Pelvic Prolapse Repair	OBG Management Supp.Sept. 2007; S1-S12
Li B, Zhu L, Lang J, Fan R,et al	Long-term Outcomes of the Tension-Free Vaginal Tape Procedure for Female Stress Urinary Incontinence: 7-Year Follow-up in China	J Min Invas Gynecol 2012; 19(2):201-205
Li X, et al.	Characterizing the ex vivo mechanical properties of synthetic polypropylene surgical mesh	J Mechanical Behavior Biomedical Materials (2014) 48-55
Liang R, Abramowitch S, et al	Vaginal Degeneration Following Implantation of Synthetic Mesh With Increased Stiffness	BJOG (2013); 120(2): 233-243
Liang R, et al	Impact of prolapse meshes on the metabolism of vaginal extracellular matrix in rhesusmacaque	Am J Obstet Gynecol 2015;212:174.e1-7.
Liang R, et al	Increasing stiffness of synthetic mesh negatively impacts vaginal connective tissue	Female Pelvic Med Reconstr. Surgery (2011) 17(5): S54-S110
Liang R, et al	Vaginal degeneration following implantation of high stiffness mesh	Female Pelvic Med Reconstr. Surgery (2011) 17(5): S54-S110
Liapis A, Bakas P, and Creatsas G.	Monarc vs. TVT-O for the treatment of stress incontinence: a randomized study	Int Urogynecol J (2008) 19:185-190
Liapis A, Bakas P, Creatsas G.	Efficacy of inside-out transobturator vaginal tape (TVTO) at 4 years follow up.	Eur J Obstet Gynecol Reprod Biol. 148 (2010) 199-201.
Liapis A, Bakas P, Creatsas G.	Burch Colposuspension and Tension-free Vaginal Tape in the Management of Stress Urinary Incontinence in Women.	Eur Urol. 41 (2002):469-473.
Liapis A, Bakas P, et al	Tension-free Vaginal Tape for Elderly Women with Stress Urinary Incontinence.	International Journal of Gynecology & Obstetrics (2006) 92, 48-51
Liapis A, Bakas P, et al	The use of oestradiol therapy in postmenopausal women after TVT-O anti-incontinence surgery.	Maturitas. 2010 May;66(1):101-6. doi: 10.1016/j.maturitas.2010.01.020. Epub 2010 Mar 16.
Liapis A, Bakas P, Giner M, et al	Tension-free vaginal tape versus tension-free vaginal tape obturator in women with stress urinary incontinence	Gynecol Obstetric Invest 62:160-164
Liebert TC, et al	Subcutaneous Implants of Polypropylene Filaments	J Biomed Mater Res 1976; 10:939-951
Liedl B, et al	A review and critical analysis of historical operations for cure of urinary stress incontinence. Part 2- abdominal sling operations	Pelviperrineology 2014; 33: 68-73

## LITERATURE

Author	Description	Journal Citation
Lim JL, Cornish A, et al	Clinical and quality-of-life outcomes in women treated by the TVT-O procedure.	BJOG. 2006 Nov;113(11):1315-20.
Lim JL, Quinlan DJ.	Safety of a new transobturator suburethral synthetic sling (TVT-O) procedure during the training phase.	J Obstet Gynaecol Can. 2006 Mar;28(3):214-7.
Lim YN, et al	Do the Advantage slings work as well as the tension-free vaginal tapes?	Int Urogynecol J (2010) 21:1157-1162
Lim YN, Muller R, et al	"Suburethral slingplasty evaluation study in North Queensland, Australia: the SUSPEND trial."	Australian and New Zealand Journal of Obstetrics and Gynaecology,45:52-9,24-Feb-05
Lin ATL, Wang SJ, et al	In vivo tension sustained by fascial sling in pubovaginal sling surgery for female stress urinary incontinence	J Urology (2005) 173: 894-897
Litwiller JP, et al	Effect of lithotomy positions on strain of the obturator and lateral femoral cutaneous nerves	Clin Anat 2004 Jan; 17(1): 45-9
Litwiller, SE et al	Presentation Number: Poster 109 Long term efficacy and safety of the Obtryx™ (Boston Scientific Corp.) sling for treatment of stress urinary incontinence in a community setting: an analysis of outcomes and quality of life	J Pelvic Med & Surg (2009) 12(5) 353
Liu PE, Su CH, Lau HH, et al	Outcome of tension-free obturator tape procedures in obese and overweight women.	Int Urogynecol J. 2011 Mar;22(3):259-63. doi: 10.1007/s00192-010-1311-1. Epub 2010 Nov 12.
Lord HE, Taylor JD, et al	A randomized controlled equivalence trial of short-term complications and efficacy of tension-free vaginal tape and suprapubic urethral support sling for treating stress incontinence.	BJU International,98:367-76 (2006)
Lowenstein L, et al	Patients' pelvic goals change after initial urogynecologic consultation	Am J Obstet Gynecol 2007; 197:640.e1-640.e3.
Lowry, F	EAU 2009 Single-incision mid-urethral sling has high cure rate for stress urinary incontinence	Medscape. Mar 31, 2009
Lucas M, Emery S, Alan W, et al	Failure of porcine xenograft sling in a randomised controlled trial of three sling materials in surgery for stress incontinence (Abstract).	Proceedings of the International Continence Society (34th Annual Meeting) and the International Urogynecological Association. 2004.
Lucas MG, et al	Guidelines on Urinary Incontinence	EUA - Full version 2013
Lucas MG, et al	Guidelines on Urinary Incontinence	Euro Assoc Urology Guidelines Pocket Version 2013
Lucas MG, et al	EAU Guidelines on Surgical Treatment of Urinary Incontinence (Short Version)	Euro Urol 2012; 62:1118-1129
Lucas, M, Bosch, R, et al.	EAU Guidelines on Surgical Treatment of Urinary Incontinence	European Urology 62 (2012) 1118-1129
Luongo JP	Infrared Study of Polypropylene	J Appl Polym Sci 1960; 3(9):302-309

## LITERATURE

Author	Description	Journal Citation
Mahajan ST, et al	Transobturator tape erosion associated with leg pain	Int Urogynecol J (2005) 17: 66-68
Maher C, Qatawneh A, et al	Laparoscopic Colposuspension or Tension-free Vaginal Tape for Recurrent Stress Urinary Incontinence and/or Intrinsic Sphincter Deficiency in a Randomized Controlled Trial.	Neurourol Urodyn 2004; 23:433-434
Mahmoud WM, et al	Migration of bacteria along synthetic polymeric fibers	J Biomater Sci Polym Edn 1993; 4(6): 567-578
Mamy L, et al	Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection	Int Urogynecol J 2011; 22:47-52
Mansoor A, Védrine N et al	Surgery of female urinary incontinence using transobturator tape (TOT): a prospective randomised comparative study with TVT (Abstract).	Neurourology and Urodynamics 22.5 (2003): 88-88.
Marcus-Braun N, Bourret A, et al	Persistent pelvic pain following transvaginal mesh surgery: a cause for mesh removal	Euro J Obstet & Gynecol and Reprod Bio 162 (2012) 224-228
Marcus-Braun N, von Theobald P	Mesh removal following transvaginal mesh placement: a case series of 104 operations.	Int Urogynecol J (2010) 21:423-430
Marinkovic S	Adjusting sling length to maximize same-day voiding	Int Braz J Urol 2006; 32: 000-000
Marinkovic SP	Short Communication: Adjusting bladder neck sling length to maximise same-day voiding	BJOG 2006; 113:1092-1095
Marks B, Goldman H	Controversies in the Management of Mesh-Based Complications: A Urology Perspective	Urol Clin N Am 39 (2012) 419-428
Marsh F and Rogerson L.	Groin abscess secondary to trans obturator tape erosion: case report and literature review.	Neurol Urodynam 26:543-546, 2007
Martinez-Fornes	A three year follow-up of a prospective open randomized trial to compare tension-free vaginal tape with Burch colposuspension for treatment of female stress urinary incontinence	Actas Urol Esp. 2009 Nov;[Deleted Object](10):1088-96
Mary C, et al	Comparison of the in vivo behavior of polyvinylidene fluoride and polypropylen sutures used in vascular surgery	ASAIO Journal 1998; 44:199-206
Masata J, Svabik K, et al	Randomized Prospective Trial of a Comparison of the Efficacy of TVT-O and TVT SECUR System in the Treatment of Stress Urinary Incontinent Women - Comparison of the Long- and Short-Term Results	Neurourol Urodyn 2011;30:805-806
Masata J, Svabik K, Hubka P, et al	ICS Abs 6 Is the fixation of single incision tape (TVT-S) as good as a transobturator tape (TVT-O)? An ultrasound study, results from randomized trial.	International Continence Society Mtg 2012
Masata J, Svabik K, Zvara K, et al	Randomized trial of a comparison of the efficacy of TVT-O and single-incision tape TVT SECUR systems in the treatment of stress urinary incontinent women--2-year follow-up.	Int Urogynecol J. 2012 Oct;23(10):1403-12.

## LITERATURE

Author	Description	Journal Citation
May, J, et al	M429 OUTCOME OF OBTRYX	Poster presentations / Inte J Gynecol & Obstet 11953 (2012) S531-S867
Mazouni, Chafika	Urinary complications and sexual function after the tension-free vaginal tape procedure	Acta Obstetricia et Gynecologica Scandinavica volume 83 Issue 10 pages 955-961 October 2004
McCracken, G.R.	Five Year Follow-Up Comparing Tension-Free Vaginal Tape and Colposuspension	Ulster Med J 2007; 76(3) 146-149
McFadden BL, et al	Patient recall 6 weeks after surgical consent for midurethral sling using mesh	Int Urogynecol J (2013) 24:2099-2104
McNanley AR, et al	Poster Presentation Abstracts 108 Recovery after robotic sacrocolpopexy: the patient's perspective	J Pelvic Med & Surg (2009) 12(5) 353
Medscape	Surgical Management of UI and Pelvic Prolapse: 2006 AUA Results	Medscape
Meier, B	Group Faults the FDA on Oversight of Devices	New York Times 04/12/2011
Mellier G, Benayed B, et al	Suburethral tape via the obturator route: is the TOT a simplification of the TVT?	Int Urogynecol J (2004) 15: 227-232
Merritt K, et al	Factors Influencing Bacterial Adherence to Biomaterials	J Biomater Appl 1991; 5: 185-203
Merritt K, et al	Tissue colonization from implantable biomaterials with low numbers of bacteria	J Biomed Mater Res 1999; 44:261-265
Merritt, K.	Factors Influencing Bacterial Adherence to Biomaterials	J Biomater Appl. 1991;5:185-203
Meschia M, Bertozzi R, et al	Peri-operative morbidity and early results of a randomised trial comparing TVT and TVT-O	Int Urogynecol J (2007) 18: 1257-1261
Meschia M, et al	Single-incision mid-urethral sling: impact of obesity on outcome.	Eur J Obstet Gynecol Reprod Biol 2013;170:571-574
Meschia M, et al	Tension-Free Vaginal Tape: Analysis of Outcomes and Complications in 404 Stress Incontinent Women	Int Urogynecol J (2001) (Suppl 2): S24-S27
Meschia M, et al	TVT-secur: a minimally invasive procedure for the treatment of primary stress urinary incontinence. One year data from a multi-centre prospective trial	Int Urogynecol J (2009) 20:313-317
Meschia M, Pifarotti P, et al	A randomized comparison of tension-free vaginal tape and endopelvic fascia plication in women with genital prolapse and occult stress urinary incontinence	Am J Obstet Gynecol. 2004 Mar;190(3):609-13.
Meschia M, Pifarotti P, et al	Tension-free Vaginal Tape (TVT) and Intravaginal Slingplasty (IVS) for Stress Urinary Incontinence: a Multicenter Randomized Trial.	Am J Obstet Gynecol. 2006 Nov;195(5):1338-42. Epub 2006 Jun 12
Meschia M, Pifarotti P, et al	A Multicenter Randomized Comparison of Tension-free Vaginal Tape (TVT) and Trans-obturator in-out Technique (TVT-O) for the Treatment of Stress Urinary Incontinence: One Year Results.	International Urogynecology Journal

## LITERATURE

Author	Description	Journal Citation
Mesens T, et al	Late erosions of mid-urethral tapes for stress urinary incontinence--need for long-term follow-up?	Int Urogynecol J Pelvic Floor Dysfunct 2007; 18(9): 1113-1114
Meyer CP, et al	Complications After Surgery for Stress Urinary Incontinence Untangling a Mesh of Uncertainties	JAMA Surgery Published online September 9, 2015: E1
Miklos JR, Chinthakana O, et al	The IUGA_ICS classification of synthetic mesh complications in female pelvic floor reconstructive surgery: A multicenter study	Int Urogynecol J (2014) 25 (Suppl 1):S140-S141
Milani R, Salvatore S, et al	Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with prolene mesh.	BJOG (2005)112:107-111
Miller D, Lucente V, et al	Prospective clinical assessment of the transvaginal mesh technique for treatment of pelvic organ prolapse-5-year results.	Female Pelvic Med Reconstr Surg 2011; 17: 139-143
Miller JR, Botros SM, et al	Comparing stress urinary outcomes of tension free vaginal tape with transobturator tape sling: a retrospective cohort study	Presented at ICS 2005, 35th annual meeting of the International Continence Society, Aug. 31-Sept. 2, 2005, Montreal, Canada.
Mirosh M and Epp A.	TVT vs laparoscopic Burch colposuspension for the treatment of stress urinary incontinence.	<a href="http://www.ics.org/Abstracts/Publish/43/00640.pdf">http://www.ics.org/Abstracts/Publish/43/00640.pdf</a>
Mischinger J, et al	Different surgical approaches for stress urinary incontinence in women	Minerva Ginecol 2013; 65: 21-8
Misrai V, Roupert M, et al	Surgical resection for suburethral sling complications after treatment for stress urinary incontinence	J Urol 2009 May;181(5):2198-202; discussion 2203
Moalli, P., et al	Tensile Properties of Five Commonly Used Mid-Urethral Slings Relative to the TVT	Int Urogynecol J (2008) 19:655-663
Moghaddam L, et al	Investigation of polypropylene degradation during melt processing using a profluorescent nitroxide probe: A laboratory-scale study	Polym Degrad Stab 2011; 96: 455-461
Montoya TI, et al	Anatomic relationships of pudendal nerve branches	Am J Obstet Gynecol 2011; 205: 504.e1-5
Moon, HB., et al	Occurrence and Accumulation Patterns of Polycyclic Aromatic Hydrocarbons and Synthetic Musk Compounds in Adipose Tissues of Korean Females.	Chemosphere. (2012) 86:485-90
Moore R, Mitchell G, et al	"ICS Abs 827 MiniArc single incision sling: 1 year follow-up on a new minimally invasive treatment for female SUI."	International Continence Society Mtg 2009
Moore RD, et al	Minimally Invasive Treatment for Female Stress Urinary Incontinence	Expert Rev Obstet Gynecol 3(2), 257-272 (2008)
Moore RD, Miklos JR.	Single incision mini-sling. 1 year follow-up on a new minimally invasive treatment for female SUI.	Int Urogyn J 2009;20(Suppl 3):S312-313 IUGA Abs 298
Moore WS, Hall AD	Late Suture Failure in the Pathogenesis of Anastomotic False Aneurysms	Annals of Surgery 172.6 (1970):1064-1068

## LITERATURE

Author	Description	Journal Citation
Morey AF, Medendorp AR, et al	Transobturator versus transabdominal mid urethral slings: a multi-institutional comparison of obstructive voiding complications	J Urology, (2006)175:1014-1017
Moride Y, et al	Under-reporting of adverse drug reactions in general practice	Br J Clin Pharmacol 1997; 43: 177-181
Morley R and Nethercliffe J.	Minimally invasive surgical techniques for stress incontinence surgery.	Best Practice & Research Clinical Obstetrics & Gynaecology ,19:925-40,07-Nov-05
Morton HC, et al	Urethral injury associated with minimally invasive mid-urethral sling procedures for the treatment of stress urinary incontinence: a case series and systematic literature search	BJOG 2009;1 16:1120-1126
Mostafa A, Agur W, et al	A multicentre prospective randomised study of single-incision mini-sling (Ajust®) versus tension-free vaginal tape-obturator (TVT-O) in the management of female stress urinary incontinence: pain profile and short-term outcomes.	Eur J Obstet Gynecol Reprod Biol. (2012);165:115-21.
Mostafa A, et al	Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: An updated systematic review and meta-analysis of effectiveness and complications	Eur Urol 2014;65:4-2-427.
Mourtzinis A, et al	Editorial comment: Advances in female stress urinary incontinence: mid-urethral slings	BJU International 2001; 98 Supp 1; 41-42
Mouzoon, N, Garome, M, et al.	Substantially Unsafe Medical Devices Pose Great Threat to Patients; Safeguards Must be Strengthened, Not Weakened	Public Citizen, February 2012
Mueller, ER	Retropubic Bladder Neck Suspensions	In H.B. Goldman (Ed.), Complications of Female Incontinence and Pelvic Reconstructive Surgery (pp. 107-114): Humana Press
Mueller, ER, et al	Are we missing an opportunity to teach future physicians about female pelvic floor disorders?	Int Urogynecol J (2009) 20:1413-1415
Muffy TM, et al	Interventional Radiologic Treatment of pelvic hemorrhage after placement of mesh for reconstructive pelvic surgery	Obstet Gynecol 2012; 119:459-62
Muir TW, Tulikangas PK, et al	The Relationship of Tension-Free Vaginal Tape Insertion and the Vascular Anatomy	Obstetrics & Gynecology,101:933-6,01-May-03
Murphy M, van Raalte H, et al	Incontinence-related quality of life and sexual function following the tension-free vaginal tape versus the ""inside-out"" tension-free vaginal tape obturator.	Int Urogynecol J (2008) 19:481-487
Murray S, et al	Urethral distortion after placement of synthetic mid urethral sling	J Urol 2011; 185:1321-1326

## LITERATURE

Author	Description	Journal Citation
Murray, S., et al	Mesh kits for anterior vaginal prolapse are not cost effective	Int Urogynecol J, 2011; 22(4), 447-452. doi: 10.1007/s00192-010-1291-1 (2011)
Mustafa M, et al	Bladder erosion of tension-free vaginal tape presented as vesical stone; management and review of literature	Int Urol Nephrol 2007; 39:453-455
N/A	"American National Standard Biological evaluation of medical devices--Part 7: Ethylene oxide sterilization residuals"	ANSI/AAMI/ISO 10993-7:2008
N/A	Hazardous Substances	CAW Health, Safety & Environment Fact Sheet, Aug 2011
N/A	"IUGA Sexual Dysfunction in Women Roundtable, June 6-8, 2008, Lago Mar Resort, Fort Lauderdale, Florida, USA"	Int Urogynecol J (2009) 20 (Suppl 1): S1-S2
N/A	Medical Devices and the Public's Health The FDA 510(k) Clearance Process at 35 Years	IOM Report Brief July 2011
N/A	Discrepancies between trial results reported on clinical trial registry and in journals	Medical Press medicalxpress.com March 11, 2014
N/A	Regulatory Issues: FDA urged to replace 510(k) process	OR Manager (2011) 27;9: 1
N/A	Emedicine - Medscape.com (2013) Burch colposuspension	
N/A	Emedicine - Medscape.com (2013) Vaginal sling procedures	
N/A	IAGE News Letter 2011-2012	
N/A	Womensdoctor.com (2013) Burch Procedure and Paravaginal Repair	
N/A	FDA.gov (2013) Stress Urinary Incontinence	
N/A	Wikipedia.org (2013) Urinary Incontinence	
N/A	Netdoctor.com (2013) Stress Urinary Incontinence - Pelvic Floor exercise	
N/A	WebMD.com (2013) Mechanical devices for Urinary Incontinence in Women	
Narang S, Han HC	Initial Experience of TVT-Abbrevio at a Tertiary Care Hospital	ICS Abs. 682
Narang, S, et al	TVT Abbrevio for management of female stress urinary incontinence - A prospective analysis over 22 months in a tertiary care hospital	Narang abstract poster
Naumann G, Lobodasch K, et al	Tension free vaginal tape (TVT) vs less invasive free tape (LIFT)-a randomized multicentric study of suburethral sling surgery.	<a href="http://www.ics.org/Abstracts/Publish/44/000481.pdf">http://www.ics.org/Abstracts/Publish/44/000481.pdf</a>
Navarro, RF, et al	Elastic properties of degraded polypropylene	J Mater Sci 2007; 42:2167-2174
Nazemi TM, Yamada B, et al	Minimum 24-Month Followup of the Sling for the Treatment of Stress Urinary Incontinence	The Journal of Urology, 179:596-9, 21-Dec-07

## LITERATURE

Author	Description	Journal Citation
Neuman M	TVT and TVT Obturator comparison of two operative procedures	European J Obstet & Gynecol and Reproduct Biology 131 (2007) 89-92
Neuman M, Sosnovski V, et al	Transobturator vs single-incision suburethral mini-slugs for treatment of female stress urinary incontinence: early postoperative pain and 3-year follow-up.	J Minim Invasive Gynecol. (2011) 18: 769-773
Neuman M.	TVT-obturator: short-term data on an operative procedure for the cure of female stress urinary incontinence performed on 300 patients.	Eur Urol. (2007) 51: 1083-1088.
Neuman M.	Perioperative Complications and Early Follow Up with 100 TVT-SECUR Procedures	The Journal of Minimally Invasive Gynecology (2008) 15: 480-484
Neuman, M, Sosnovski V, et al	Comparison of two inside-out transobturator suburethral sling techniques for stress incontinence: Early postoperative thigh pain and 3-year outcomes	Int J Urol (2012) 19: 1103-1107
Nezhat FR, et al	Robotic-assisted laparoscopic transection and repair of an obturator nerve during pelvic lymphadenectomy for endometrial cancer	Obstet Gynecol 2012; 119: 462-4
Nguyen JN and Burchette RJ.	Outcome after anterior vaginal prolapsed repair: a randomized controlled trial.	Obstetrics & Gynecology (2008),111 (4):891-898
Nguyen JN, Jakus-Waldman SM, et al	Perioperative complications and reoperations after incontinence and prolapse surgeries using prosthetic implants.	Obstetrics & Gynecology, (2012)119(3):539-546
NICE	Urinary Incontinence. The management of urinary incontinence in women Issued: September 2013	NICE clinical guideline 171
NICE	Clinical Guideline 171 Urinary Incontinence: The management of urinary incontinence in women	NICE clinical guideline 171 (2013)
NICE	Urinary incontinence: The management of urinary incontinence in women	NICE clinical guideline 171 (2013)
NICE	2013-NICE-urinary incontinence p24- Synthetic tapes	NICE clinical guideline 171 pg 24
NICE	Eighth Report of Session 2012-13 Volume II	
NICE Guidance	<a href="http://guidance.nice.org.uk/index.jsp?action=article&amp;o=32572">http://guidance.nice.org.uk/index.jsp?action=article&amp;o=32572</a>	
Nieminen K, Hiltunen R, et al	"Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up"	Am J Obstet Gynecol,(2010)203:235.e1-8
Nilsson C.G., et al	Reprint: Long-term Results of the Tension-Free Vaginal Tape (TVT) Procedure for Surgical Treatment of Female Stress Urinary Incontinence	Int Urogynecol J (2001)(Supp. 2):S5-S8 Eth.Mesh.00159481-00159484
Nilsson CG, et al	Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence	Int Urogynecol J 24, 1265-1269 (2013)

## LITERATURE

Author	Description	Journal Citation
Nilsson CG, et al	Seven year follow up of the tension free vaginal tape procedure for treatment of urinary incontinence	Obstet Gynecol 2004; 104: 1259-62
Nilsson, C	Creating a gold standard surgical procedure: the development and implementation of TVT	Int Urogynecol J DOI 10.1007/s00192-014-2616-2 (2015)
Nilsson, CG, et al	Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence	Int Urogynecol J (2008) 19:1043-1047
Nilsson, CG., et al	Long-term Results of the Tension-Free Vaginal Tape (TVT) Procedure for Surgical Treatment of Female Stress Urinary Incontinence	Int Urogynecol J (2001) (Suppl 2): S5-S8
Noblett KL, Shen B, et al	Lynx midurethral sling system: a 1-year prospective study on efficacy and safety	5479411
Norton, P	New technology in gynecologic surgery. Is new necessarily better?	Obstet & Gynecol (2006)108(3)2:707-708
Nossier S, et al	Presentation Number: Poster 30 Safety and efficacy of the Solyx™ single-incision sling system	Female Pelvic Medicine & Reconstructive Surgery (2010) 16(5)2:S110-S1111
Novara G, et al	Tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials of effectiveness	European Urol 52 (2007) 663-679
Novara G, Galfano A, et al	Critical Assessment of Pelvic Floor Surgical Reconstruction Outcome	EAU-EBU Update Series 4 (2006) 202-213
Novara G, Galfano A, et al	Complication rates of tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices	Eur Urol (2008) 53: 288-309
Nygaard I, Barber MD, et al	Prevalence of symptomatic pelvic floor disorders in US women.	JAMA (2008); 300(11):1311-1316
Nygaard I, Brubaker L, et al	Long-term Outcomes Following Abdominal Sacrocolpopexy for Pelvic Organ Prolapse	JAMA (2013);309(19):2016-2024,
Nygaard IE, McCreery R, et al	Abdominal sacrocolpopexy: a comprehensive review.	Obstet & Gynecol (2004)104(4):805-823
Nygaard, I	Approval Process for Devices and Mesh for Surgical Treatment of Pelvic Organ Prolapse and Urinary Incontinence	Clinical Obstet and Gynecol (2013) 56(2): 229-231
Obadal M, et al	Structure evolution of $\alpha$ - and $\beta$ -polypropylenes upon UV irradiation: A multi-scale comparison	Polym Degrad Stab 2005; 88(3):532-539.
Ogah J, Cody DJ, and Rogerson L.	Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women	Cochrane Database of Systematic Reviews ,CD006375,07-Oct-09

## LITERATURE

Author	Description	Journal Citation
Ogah J, Cody DJ, and Rogerson L.	Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women: a short version Cochrane Review	Neurourology and Urodynamics(2011)30:284-291
OHSU	Clinical trial results inconsistently reported among journals, government website _ News _ OHSU	03/31/14 Portland, Ore.
Okulu E, et al	The use of three types of synthetic mesh materials in the surgery for stress incontinence: the clinical results	IUGA Abstract 765
Okulu E, et al	Use of three types of synthetic mesh material in sling surgery: A prospective randomized clinical trial evaluating effectiveness and complications	Scandinavian Journal of Urology, 2013; 47: 217-224
Okulu E, Kayigil O, et al	Use of three types of synthetic mesh material in sling surgery - a prospective randomized clinical trial evaluating effectiveness and complications	Scandinavian J Urology 2013; 47: 217-224
Oliveira R, Botelho F, et al	Exploratory Study Assessing Efficacy and Complications of TVT-O, TVT-Secur, and Mini-Arc: Results at 12-Month Follow-up.	European Urology (2011) 59: 940-44
O'Rourke PJ	Review Sling techniques in the treatment of genuine stress incontinence	BJOG 2000; 107(2): 147-156
Ortega-Castillo V and Neri-Ruz ES.	Chapter 15: Surgical Complications with Synthetic Materials	Urinary Incontinence (book published by InTech),241-62,02-Apr-12
Osborn, D.J. et al.	Analysis of patient and technical factors associated with midurethral sling mesh exposure and perforation	Int J Urol (2014) 21, 1167-1170
Osmundsen B, et al	Tension-free vaginal tape failure after robotic sacrocolpopexy and tension-free vaginal tape for concomitant prolapse and stress incontinence	Female Pelvic Med Reconstr Surg 2015;21:244-248
Osterberg B	Effect of suture materials on bacterial survival in infected wounds. An experimental study	Acta Chir Scand 1979; 145(7):431-434 abstract
Osterberg B	Enclosure of bacteria within capillary multifilament sutures as protection against leukocytes	Acta Chir Scand 1983; 149(7):663-668 abstract
Osterberg B	Influence of capillary multifilament sutures on the antibacterial action of inflammatory cells in infected wounds	Acta Chir Scand 1983; 149(8):751-757 abstract
Osterberg, B., et al	Effect of Suture Materials on Bacterial Survival in Infected Wounds. An Experimental Study	Acta Chir Scand. 1979; 145(7):431-4
Ostergard DR	Lessons from the past: directions for the future Do new marketed surgical procedures and grafts produce ethical, personal liability, and legal concerns for physicians?	Int Urogynecol J (2007) 18:591-598
Ostergard DR	Degradation, infection and heat effects on polypropylene mesh for pelvic implantation: what was known and when it was known	Int Urogynecol J (2011) 22:771-774

## LITERATURE

Author	Description	Journal Citation
Ostergard, DR	Vaginal mesh grafts and the Food and Drug Administration	Int Urogynecol J (2010) 21: 1181-1183
Ostergard, DR	Polypropylene Vaginal Mesh Grafts in Gynecology	Obstet Gynecol 1020; 116:962-966
Oswald HJ, et al	The deterioration of Polypropylene by Oxidative Degradation	Polym Eng Sci 1965; 5(3):152-158
Ozog Y., et al	Shrinkage and biomechanical evaluation of lightweight synthetics in a rabbit model for primary fascial repair	Int Urogynecol J published online: 12 May 2011
Ozog Y., et al	Weight of Polypropylene Mesh is Not the Only Property Defining in Vivo Mesh Biomechanics	IUGA Abstract 47
Palma P, et al	Monoprosthesis for anterior vaginal prolapse and stress urinary incontinence: midterm results of an international multicentre prospective study	Int Urogynecol J (2011) 22:1535-1541
Palma P, et al	Arcus to acrus microsling: technique and preliminary results	Int Urogynecol J Accepted 23 February 2008
Palva K, Rinne K, et al	A randomized trial comparing tension-free vaginal tape with tension-free vaginal tape-obturator: 36-month results	Int Urogynecol J(2010) 21: 1049-1055
Paraiso MF, Walters MD, et al	Laparoscopic Burch Colposuspension versus Tension-free vaginal tape: a randomized trial	Obstetrics & Gynecology (2004)104(6):1249-1258
Parden AM, Gleason JL, et al	Incontinence outcomes in women undergoing primary and repeat midurethral sling procedures.	Obstet Gynecol (2013);121(201):273-278
Pariente, JL.	Mechanical evaluation of various suburethral tapes used for the treatment of stress urinary incontinence.	(2005) Progres en Urologie, 15 (6), pp. 1106-1109 (French - abstract only)
Parker-Autry C, et al	Measuring outcomes in urogynecological surgery: "perspective is everything"	Int Urogynecol J (2013) 24:15-25
Parnell, BA, et al	Gentiofemoral and Perineal Neuralgia After Transobturator Midurethral Sling	Obstet Gynecol. 2012 Feb; 119(2 Pt 2):428-31
Peoples, AJ., et al	Determination of Volatile Purgeable Alogenated Hydrocarbons in Human Adipose Tissue and Blood Serum	Bull. Environm. Contam. Toxicol. 23, 244-249 (1979)
Persson J, Teleman P, et al	"Cost-analyzes based on a prospective, randomized study comparing laparoscopic colposuspension with a tension-free vaginal tape procedure. "	Acta Obstetricia et Gynecologica Scand 2002 Nov; 81(11):1066-73
Peters A, et al	Referral Patterns for Pelvic Floor Surgical Prosthesis Complications: From Symptom Onset and Initial Treatments to Evaluation at a Tertiary Care Center	Female Pelvic Med Reconstr Surg 2015;21: 116-120
Petri E, Ashok K	Complications of synthetic slings used in female stress urinary incontinence and applicability of the new IUGA-ICS classification	Euro Obstet & Gynecol and Reproductive Biology J 165 (2012) 347-351

## LITERATURE

Author	Description	Journal Citation
Petri E, Ashok K	Comparison of late complications of retropubic and transobturator slings in stress urinary incontinence	Int Urogynecol J (2012) 23:321-325
Petros P	Letter to the Editor - A basis for long-term midurethral tape complications	Neurology and Urodynamics 2011;130: 199-200
Petros P, et al	Evolution of midurethral and other mesh slings - a critical analysis.	Neurology Urodynamics 2012;9999:1-7
Petros P, et al	A basis for long-term midurethral tape complications	Neurourology and Urodynamics (2011) 30: 199-200
Petros P, Richardson PA.	Midurethral tissue fixation system sling - a "micromethod" for cure of stress urinary incontinence - preliminary report.	Aust NZ J Obstet Gynaecol 2005;45:372-375
Petros PE and Ulmsten UI.	An integral theory of female urinary incontinence: Experimental and clinical considerations	Acta Obstet Gynecol Scand (1990) 69 Suppl 153:7-31
Petros PEP, Richardson PA.	Midurethral tissue fixation system (TFS) sling for cure of stress incontinence - 3 year results.	Int Urogynecol J 2008;19:869-871.
Pham S, Rodeheaver GT, et al	Ease of Continuous Dermal Suture Removal	J Emergence Med 1990; 8:539-543
Pham T, et al	New pelvic symptoms are common after reconstructive pelvic surgery	Am J Obstet Gynecol 2009;200:88.e1-88.e5.
Phé V, Zimmern P, et al	Outcome measures for SUI can we minimally agree?	World J Urol published online 20 March 2014
Phillips L, Flood CG, Schulz JA.	Case report of tension-free vaginal tape associated bowel obstruction and relationship to body habitus.	Int Urogyn J 2009;20:367-368
Pierre, Gounon	Abstract "Histological analysis of peri prothetic tissues of mesh explanted for complication after SUI or POP surgery"	Universite de Nice Sophia Antipolis France
Pikaart DP, et al	Laparoscopic removal of pubovaginal polypropylene tension-free tape slings	JSLS (2006) 10:220-225
Pizarro-Berdichevsky JA, et al	Vaginal fibroblast inflammation by in vitro exposure to polypropylene type I mesh: an inert material?	Int Urogynecol J 2012; 23(Suppl 2): S110-S111
Pizarro-Berdichevsky, et al	Removal of obstructing synthetic sling from a urethra: English and Spanish version	Int Urogynecol J 2016; 27:1929 doi:10.1007/s00192-016-3098-1
Pocock ST	The pros and cons of noninferiority trials	Fundamental & Clinical Pharmacol 17 (2003) 483-490
Polichetti M, et al	"IUGA Abs. 557 SUS(suburethral support): a new technique for short suburethral sling application"	Int Urogyn J 2009;20(Suppl 3):S477-478
Porena M, Costantini E, et al	Tension-free vaginal tape versus transobturator tape as surgery for stress urinary incontinence: results of a multicentre randomised trial.	Eur Urology, (2007)52:1481-1490
Portney S	Advertising and Promotion of Medical Devices	J Health Law (2006) 39(2) 265-282
Postlethwait RW	Long-Term Comparative Study of Nonabsorbably Sutures	Ann Surg (1970) 171(6): 892-898

## LITERATURE

Author	Description	Journal Citation
Postlethwait RW	Five Year Study of Tissue Reaction to Synthetic Sutures	Ann Surg 190(1):54-57 (1979)
Presthus JB, VanDrie D, et al	Short-Term Assessment of MiniArc Single Incision for Treatment of Stress Urinary Incontinence	The Journal of Minimally Invasive Gynecology,15:28S-9S Abstract 103,01-Nov-08
Prien-Larsen JC, et al	Influence of TVT properties on outcomes of midurethral sling procedures: high-stiffness versus low-stiffness tape	Int Urogynecol J (2016) 27:1039-1045
Prien-Larsen JC, et al	Reply to the letter to the editor on Prien-Larsen et al.: Influence of TVT properties of midurethral sling Procedures: high-stiffness versus low-stiffness tape	Int Urogynecol J (2016) 27:1941
Propex Geotextile Systems	Propex EB-405 Durability of Polypropylene	Propex EB-405
Public Citizen	Substantially Unsafe Medical Devices Pose Great Threat to Patients: Safeguards Must be Strengthened, Not Weakened	Public Citizen, February 2012
Pukall CF, et al	Neural correlates of painful genital touch in women with vulvar vestibulitis syndrome	Pain 2005 May; 115(1-2):118-27
Rabello MS, et al	The role of physical structure and morphology in the photodegradation behaviour of polypropylene	Polym Degrad Stab 1997; 56:55-73
Rader, CP, et al	Cytokine response of human macrophage-like cells after contact with polyethylene and pure titanium particles	J Arthroplasty 1999; 14(7):840-848
Ralph G, et al	The failed idea of a "gold standard"	Int Urogynecol J (2015) 26:1405-1406
Rardin CR, Moore R, et al	Recurrent Thigh Abscess with Necrotizing Fasciitis from a Retained Transobturator Sling Segment	The Journal of Minimally Invasive Gynecology,16:84-7,01-Jan-09
Ravve, C.	Principles of Polymer Chemistry	2000, Revised edition
Raz S	Expert: Synthetic materials are preferred for stress incontinence surgery	Urology Times April 08, 2007
Rechberger T, et al	A randomized comparison between monofilament and multifilament tapes for stress incontinence surgery	Int Urogynecol J Pelvic Floor Dysfunct. 2003 Dec;14(6):432-6. Epub 2003 Nov 25
Rechberger T, Wrobel A, et al	"The tissue reaction to polypropylene mono-et multifilamentous tape used in surgical techniques of stress urinary incontinence treatment."	Gin Pol 2003;74(9):1008-1013
Rees PM, et al	Sexual function in men and women with neurological disorders	Lancet 2007; 369: 512-525
Reingruber E, et al	Identification of degradation products of antioxidants in polyolefins by liquid chromatography combined with atmospheric pressure photoionisation mass spectrometry	Polym Degrad Stab 2010; 95:740-745

## LITERATURE

Author	Description	Journal Citation
Reisenauer C, Kirschniak A, et al	Transobturator tape inside-out. A minimally invasive treatment of stress urinary incontinence: surgical procedure and Anatomical considerations	European Journal of Obstetrics & Gynecology and Reproductive Biology(2006) 127: 123-129
Reisenauer C, Shiozawa T, et al	Anatomic study of prolapse surgery with nonanchored mesh and a vaginal support device	Obstet Gynecol 2010; 203:1.e1-1.e7
Renganathan A, Basu M, Duckett J.	A series of Advantage suburethral slings	J Obstet Gynaecol Aug 2011;31:521-523
Reynolds WS, et al	Obturator foramen dissection for excision of symptomatic transobturator mesh	J Urology (2012) 187: 1680-1684
Rezapour M, et al.	Tension-Free Vaginal Tape (TVT) in Stress Incontinent Women with Intrinsic Sphincter Deficiency (ISD) -- A Long-Term Follow-Up	Int Urogynecol J (2001) (Suppl 2): S12-S14
Rezapour M., et al	Tension-Free Vaginal Tape (TVT) in Women with Recurrent Stress Urinary Incontinence - A Long-term Follow up	Int Urogynecol J (2001) (Suppl 2):S9-S11
Rezapour, M., et al	Tension-Free Vaginal Tape (TVT) in Women with Mixed Urinary Incontinence -- A Long-Term Follow-Up	Int Urogynecol J (2001) (Suppl 2): S15-S18
Riachi L	A New Minimally Invasive Treatment Option for Stress Urinary Incontinence in Woman: TVT Abbrevio, a Shorter Sling with an Inside-out Transobturator Approach	Surg Technol Int (2013) 23: 176-180 ETH.MESH.12840997
Rice NT, Hu Y, et al	Pelvic mesh complications in women before and after the 2011 FDA public health notification	Female Pelvic Med Reconstr Surg (2013);19:33-338
Richter HE, et al	Non-surgical management of stress urinary incontinence: ambulatory treatments for leakage associated with stress (ATLAS) trial	Clinical Trials 2007; 4: 92-101
Richter HE, et al	The Impact of Obesity on Urinary Incontinence Symptoms, Severity, Urodynamic Characteristics and Quality of Life	J Urol 2010; 183: 622-628
Richter HE, et al	Predictors of Treatment Failure 24 Months After Surgery For Stress Urinary Incontinence	J Urol. 2008 March ; 179(3): 1024-1030.
Richter HE, et al	Retropubic versus Transobturator Midurethral Slings for Stress Incontinence	N Engl J Med 2010 362;22
Ridgeway B, Arias B, and Barber M.	Variation of the obturator foramen and pubic arch of the female bony pelvis	The American Journal of Obstetrics & Gynecology,198:546.e1-4,01-May-08
Rigaud J, Delavierre D,et al	Management of chronic pelvic and perineal pain after suburethral tape placement for urinary incontinence	Prog Urol. 2010 Nov;20(12):1166-74. Epub 2010 Oct 20. Review. French
Rignaud J, et al	Functional results after tape removal for chronic pelvic pain following tension-free vaginal tape or transobturator tape	J Urology 2010;185:610-615

## LITERATURE

Author	Description	Journal Citation
Rignaud J, Pothin P, et al	Functional Results After Tape Removal for Chronic Pelvic Pain Following Tension-Free Vaginal Tape or Transobturator Tape	J Urology (2010) 184: 610-615
Rinne K, Laurikainen E, et al	A randomized trial comparing TVT with TVT-O: 12-month results.	The International Urogynecology Journal,19:1049-54,29-Mar-08
Riva D, Sacca V, Tonta A, et al.	T.V.T. versus T.O.T.: A Randomized Study at 1-year Follow-up.	International Urogynecology Journal, 2006 Sept 17(2) Supp: 57-100
Rivista Italiana di Colon-Proctolog	Pelviperineology A multidisciplinary pelvic floor journal	Vol. 33 - N. 3 Sptember 2014
Robert M, et al	Patient expectations, subjective improvement and objective cure: is there a difference between the transobturator tape and the tension free vaginal tape procedure? (Abstract)	Abstract 217
Robinson D., et al	What Women Want - Their Interpretation of the Concept of Cure	Journal of Pelvic Medicine & Surgery, Vol. 9 Issue 6, pp. 273-277, 2003
Robinson GA, et al	Motor neuron target selectivity and survival after prolonged axotomy	Restor Neurol Neurosci. 2013 Jan 1;31(4):451-60
Rodríguez LV, et al	Prospective analysis of patients treated with distal urethral polypropylene sling for symptoms of stress urinary incontinence: surgical outcome and satisfaction determined by patient driven questionnaires	J Urology 2003;170: 857-863
Rodríguez LV, et al	Polypropylene sling for the treatment of stress urinary incontinence	Urology 2001; 58: 783-785
Rogers AS, et al	Physician knowledge, attitudes, and behavior related to reporting adverse drug events	Arch Intern Med 1988 Jul: 148(7): 1596-600
Rogers RG	Urinary Stress Incontinence in Women	N Engl J Med 2008; 358:1029-36
Rogo-Gupta L, et al	Symptom Improvement After Prolapse and Incontinence Graft Removal in a Case Series of 306 Patients	Female Pelvic Medicine & Reconstructive Surgery 2015; 21(6):319- 324
Rogo-Gupta L, et al	Complications of mesh-augmented pelvic organ prolapse and incontinence repairs: Case series of 319 procedures	University of California, Los Angeles ABSTRACT
Rogo-Gupta, L., Raz, S.	Pain Complications of Mesh Surgery.	In H.B. Goldman (Ed.), Complications of Female Incontinence and Pelvic Reconstructive Surgery (pp. 87-105): Humana Press. (2013)
Rogowski A, Bienkowski, et al	Mesh retraction correlates with vaginal pain and overactive bladder symptoms after anterior vaginal mesh repair	Int Urogynecol J (2013) 24:2087-2092

## LITERATURE

Author	Description	Journal Citation
Rosa DS, et al	The use of optical microscopy to follow the degradation of isotactic polypropylene (iPP) subjected to natural and accelerated ageing	Polym Test 2005; 24:1022-1026
Rosch R, et al	Mesh implants In hernia repair. Inflammatory cell response in a rat model.	Eur Surg Res (2003)35(3): 161-6
Ross S, et al	Incontinence-specific quality of life measures used in trials of treatments for female urinary incontinence: a systematic review	Int Urogynecol J (2006) 17(3): 272-85
Ross S, et al	Ethical issues associated with the introduction of new surgical devices, or just because we can, doesn't mean we should	June JOGC Juin 2008 508-513
Ross S, Robert M, Lier D, et al	Surgical Management of Stress Urinary Incontinence in Women: Safety, Effectiveness, and Cost-Utility of Trans-Obturator Tape (TOT) versus Tension-free Vaginal Tape (TVT) Five Years After a Randomized Surgical Trial.	BMC Women's Health 2011, 11:34
Ross S, Robert M, Swaby C, et al	Transobturator Tape Compared With Tension-Free Vaginal Tape for Stress Incontinence	Obstetrics & Gynecology,114:1287-94,01-Dec-09
Roth, Ted M.	Management of persistent groin pain after transobturator sling	Int Urogynecol J (2007) 18:1371-1373 doi: 10.1007/s00192-007-0365-1
Roumeguère T, Quackels T, et al	Trans-obturator vaginal tape (TOT) for female stress incontinence: one year follow-up in 120 patients	European Urology (2005) 48: 805-809
Russell R	Zimmern cites shortcomings in published outcomes for anti-incontinence surgery	Newsroom Center Times, March 28-31, 2011
Sacomen D, et al	Effects of polyethylene particles of tissue surrounding knee arthroplasties in rabbits	J Biomed Mater Res Part B: Appl Biomater 1998; 43:123-130
Salvador MD, et al	Evaluation of chemical degradation of commercial polypropylene	J Mater Process Technol 2003;143-144: 693-697
Sand PK	Sumit Trial Outcomes: Clinical Insights Into Percutaneous Tibial Nerve Stimulation	Abstracts Female Pelvic Med & Reconstr Surg (2011) 17(5): S2
Sangster P, et al	Biomaterials in urinary incontinence and treatment of their complications	Indian J Urol 2010; 26(2): 221-229
Sangster P, et al	Biomaterials in urinary incontinence and treatment of their complications	Indian J Urol 2010; 26:221-229
Santavirta S, et al	Biocompatibility of polyethylene and host response to loosening cementless total hip replacement	Clin Orthop Relat Res 1993; 297:100-110
Santerre JP, et al	Enzyme-biomaterial interactions - effect of biosystems on degradation of polyurethanes	J Biomed Mater Res 1993; 27:97-209
Santoro M, Gorrie TM	Ethics and the Pharmaceutical Industry	Eds New York: Cambridge University Press 2005

## LITERATURE

Author	Description	Journal Citation
Sarsotti C, et al	The transobturator tape procedure for stress urinary incontinence: results of an Argentinean multicenter experience	Int Urogynecol J (2007) 18 (Suppl I):S107-S244 Abst 375
Sayer T, Lim J., et al	Medium-term clinical outcomes following surgical repair for vaginal prolapse with tension-free mesh and vaginal support device	Int Urogynecol J DOI 10.1007/s00192-011-1600-3
Scales, J.T.	Tissue reactions to synthetic materials.	Proc R Soc Med, 46:647-652.
Scheiner D, Betschart C, et al	Retropubic TVT vs. Transobturator Outside-in TOT and TVT-O: One-year results from our prospective randomized study.	Neurourology and Urodynamics Eth.Mesh.00587443-00587444
Scheiner DA, et al	Twelve months effect on voiding function of retropubic compared with outside-in and inside-out transobturator midurethral slings	Int Urogynecol J 2012 Feb;23(2):197-206
Schierlitz L, Dwyer P, et al	A randomized controlled study to compare tension free vaginal tape (TVT) and Monarc trans-obturator tape in the treatment of women with urodynamic stress incontinence (USI) and intrinsic sphincter deficiency (ISD): the three year follow up.	Int Urogynecol J (2010) 21 (Suppl 1):S1-S428
Schierlitz L, Dwyer P, et al	A prospective randomised controlled trial comparing vaginal prolapse repair with and without tensionfree vaginal tape (TVT) in women with severe genital prolapse and occult stress incontinence: long term follow up.	Int Urogynecol J (2010) 21 (Suppl 1):S1-S428
Schierlitz L, Dwyer PL, et al	Effectiveness of tension-free vaginal tape compared with transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency: a randomized controlled trial	Obstet Gynecol (2008)112:1253-1261
Schierlitz LHE, Dwyer PL, et al	A randomised controlled study to compare tension free vaginal tape (TVT) and Monarc transobturator tape in the treatment of women with urodynamic stress incontinence (USI) and intrinsic sphincter deficiency (Abstract no. 032).	Int Urogynecol J (2010) 21 (Suppl 1):S1-S428
Schimpf, M.O. et al.	Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis	Am J Obstet Gynecol 211, 71 e1-71 e27 (2014)
Schneider, H.	Long-Term Performance of Polypropylene Geosynthetics	Durability and Aging of Geosynthetics, edited by R.M. Koerner, Elsevier Applied Science, 1989, pp. 95-109
Schoolenberg GE	A fracture mechanics approach to the effects of UV-degradation on polypropylene	J Mater Sci 1988; 23:1580-1590
Schoolenberg GE, et al	Ultra-violet degradation of polypropylene: 2. residual strength and failure mode in relation to the degraded surface layer	Polym 1991; 32(3):438-444
Schoolenberg GE, et al	Ultra-violet degradation of polypropylene: 1. degradation profile and thickness of the embrittled surface layer	Polymer 1991; 32(3):432-444

## LITERATURE

Author	Description	Journal Citation
Schraut W, et al	TNF gene expression in monocytes of low and high responder individuals	Cytokine 1997; 9(3):206-211
Scottish News	Mesh surgery scandal: Controversial implants to be banned by Dumfries and Galloway health board	Scottish News article
Sekiguchi Y, et al	Outpatient mid urethral tissue fixation system sling for urodynamic stress urinary incontinence: 1-year results.	J Urol 2009;182:2810-283.
Serati M, et al	TVT-O for the treatment of pure urodynamic stress incontinence: efficacy, adverse effects, and prognostic factors at 5-year follow-up	European Urology 63 (2013) 872-878
Serati M, Salvatore S, et al	Surgical treatment for female stress incontinence: What is the gold-standard procedure?	Int Urogynecol J 2009;20:619-621
Serati, M.	Tension-free Vaginal Tape for the Treatment of Urodynamic Stress Incontinence: Efficacy and Adverse Effects at 10- Year Follow-Up	Eur Urol 2012;61: 939-946
Serati, M.	The Impact of the Mid-Urethral Slings for the Treatment of Stress Urinary Incontinence on Female Sexuality.	J Sex Med 2009; 6:1534-1542
Serbetci K, et al	Effects of resterilization on mechanical properties of polypropylene meshes	Am J of Surg 2007; 194:375-379
Serels S, et al	Preliminary findings with the Solyx™ single-incision sling system in female stress urinary incontinence	Int Urogynecol J (2010) 21:557-561
Serels S, et al	Long term follow up of the Solyx single incision sling in the treatment of female stress urinary incontinence (SUI)	Open J Urology 2014, 4, 13-17
Serels S, et al	Safety and efficacy of the Solyx single-incision sling for the treatment of stress urinary incontinence. Preliminary results	Urotoday Int J. 2011 Feb;4(1):art5
Serels S.	Cadaveric assessment of synthetic mid-urethral sling placement.	Open J Urol 2011;1:19-24
Sevegney MS, et al	FTIR Spectroscopic Investigation of Thermal Effects in Semi-Syndiotactic Polypropylene	J Polym Sci: Part B: Polym Physics 2005 43; 439-461
Shah, K, Nikolavsky, D, et al.	Surgical management of lower urinary mesh perforation after mid-urethral polypropylene mesh sling: mesh excision, urinary tract reconstruction and concomitant pubovaginal sling with autologous rectus fascia	Int Urogynecol J DOI 10.1007/s00192-013-2146-3 (2013)
Shah, S.M.	Impact of Vaginal Surgery For Stress Urinary Incontinence On Female Sexual Function: Is The Use Of Polypropylene Mesh Detrimental?	Urology (2005) 65: 270-274
Shameem A, et al	Measurement of transurethral bladder neck displacement during tension-free vaginal tape procedure	Int Urogynecol J (2011) 22:721-724

## LITERATURE

Author	Description	Journal Citation
Sharifiaghdas F and Mortazavi N.	Tension-free vaginal tape and autologous rectus fascia pubovaginal sling for the treatment of urinary stress incontinence: a medium-term follow-up	Med Princ Pract 2008; 17:209-214
Shaw JS, et al	Decreasing transobturator sling groin pain without decreasing efficacy using TVT-Abbrevio	Int Urogynecol J 2015;26:1369-1372
Shaw JS, Jeppson PC, et al	Incidence of Postoperative Thigh Pain after TVT Obturator and TVT Abbrevio	J Min Invas Gynecol Abstracts (2014) 21: S52
Shaw JS, Rardin PC, et al	Effect of TVT-O Abbrevio on Post-Operative Groin Pain	J Min Invas Gynecol Abstracts (2014) 21: S27-28
Shepherd J, Feola A, et al	Uniaxial Tensile Properties of Seven Vaginally Implanted Meshes for Pelvic Organ Prolapse	IUGA Abstract
Shepherd JP, et al	Uniaxial biomechanical properties of seven different vaginally implanted meshes for pelvic organ prolapse	Int Urogynecol J (2012) 23:613-620
Sheyn D, et al	Tobacco use as a risk factor for reoperation in patients with stress urinary incontinence: a multi-institutional electronic medical record database analysis	Int Urogynecol J 2015;26(9):1379-1384
Shindel AW, et al	Urethral slings placed by the transobturator approach: evolution in the technique and review of the literature	Curr Urol Rep 2005; 6(5):385-92
Simsiman AJ, Powell CR, Stratford	Suburethral sling materials: best outcome with autologous tissue	Am J Obstet and Gynecol (2005)193:2112-6
Sirls, LT, et al	Factors Associated With Quality of Life in Women Undergoing Surgery for Stress Urinary Incontinence	J Urology 2010; 184: 2411-2415
Sivanesan K	Comment on "tvt and tvf-obturator: comparison of two operative procedures"	Eur J Obstet Gynecol Reprod Biol 131 (2007) 87-90
Sivaslioglu AA, et al	A prospective randomized controlled trial of the transobturator tape and tissue fixation mini-sling in patients with stress urinary incontinence: 5-year results	J urology (2012) 188: 194-199
Sivaslioglu AA, et al	A prospective randomized controlled trial of the transobturator tape and tissue fixation system minisling in 80 patients with stress urinary incontinence - 3 year results	Pelviperrineology 2010;29:56-59.
Skala C, Renezedder K, et al	The IUGA ICS classification of complications of prosthesis and graft insertion	Int Urogynecol J (2011) 22:1429-1435
Skala CE, Renezedder K, et al	Mesh-complications following prolapse surgery: management and outcome	Euro Obstet & Tynecol and Reprod Biology J 159 (2011) 453-456
Skypunch, OW	Giant Papillary Conjunctivitis from an Exposed Prolene Suture	Can. J. Ophthalmology, 1986; 21(5:189-192)
Smith JJ, et al	Long-term outcomes and review of complications in 75 patients with Boston Scientific Advantage mesh in mid-urethral slings	www.bostonscientific.com

## LITERATURE

Author	Description	Journal Citation
Smith PP, et al	Comparison of single-incision mid-urethral tape (Ophira™) and transobturator tape (Obtryx™) sub-urethral sling procedures for female stress urinary incontinence	JCMR 2013 5(5) 58-61
Smith R, et al	The enzymatic degradation of polymers in vivo	J Biomed Mater Res 1987; 21:991-1003
Smith R, et al	The biodegradation of poly(ether urethanes)	J Biomed Mater Res 1987; 32:1149-1166
Smith, SE, et al	Materials characterization of explanted polypropylene hernia mesh: Patient factor correlation	Journal of Biomaterials Applications 2015; 0(0) 1-10
Song YF, Huang HJ, Xu B, et al	[Comparative study of tension-free vaginal tape and fascia lata for stress urinary incontinence]. [Chinese].	Zhonghua Fu Chan Ke Za Zhi. 2004 Oct;39(10):658-61. Chinese.
Songara, RK et al	Need for harmonization of labeling of medical devices: a review	J Adv Pharm Technol Res. 1020 Apr-Jun; 1(2): 127-144
Sound Urological Associates	Women's Health webpage	Sound Urology Webpage <a href="http://soundurology.com/womens-health/">http://soundurology.com/womens-health/</a> 2/16/2015
Spinosa J, Dubuis P, and Riederer	Transobturator surgery for female stress incontinence: a comparative anatomical study of outside-in vs inside-out techniques	BJU International,100:1097-102,14-Sep-07
Stanton SL et al.	Some Reflections on Tension-Free Vaginal Tape - A New Surgical Procedure for Treatment of Female Urinary Incontinence	Int Urogynecol J (2001) (Suppl 2): S1-S2
Starr DS, Weatherford ST, et al	Suture Material as a Factor in the Occurrence of Anastomotic False Aneurysms	Arch Surg April 1979; 114: 412-415
Staskin DR, Plzak L	Synthetic Slings: Pros and Cons	Current Urology Reports 2002, 3:414-417
Steege, J.F.	Evaluation and Treatment of Dyspareunia	Obstetrics Y Gynecology: May 2009- Volume 113- Issue 5- pp 1124-1136
Stephens C, Zimmern PE	Expansion of role of web based networks to mesh complications	World J Urol published online 20 July 2014
Sternschuss G, et al	Post-implantation alterations of polypropylene in the human	J Urol 2012; 188: 27-32
Strasberg SM, et al	The accordion severity grading system of surgical complications	Annals of Surgery 2009; 250(2):177-186
Strömberg E, et al	The effect of biodegradation on surface and bulk property changes of polypropylene, recycled polypropylene and polylactide biocomposites	Inter Biodeterior Biodegradation 2009; 63:1045-1053
Strus M, et al	The in vitro effect of hydrogen peroxide on vaginal microbial communities	FEMS Immunol Med Microbiol 2006; 48:56-63
Strus, M., et al	The In Vitro Effect of Hydrogen Peroxide on Vaginal Microbial Communities	FEMS Immunol Med Microbiol. 2006 Oct;48(1):56-63

## LITERATURE

Author	Description	Journal Citation
Strus, M., et al	Hydrogen Peroxide Produced by Lactobacillus Species as a Regulatory Molecule for Vaginal Microflora	Med Dosw Mikrobiol 2004;56:67-77
Sultana CJ, et al	The state of residency training in female pelvic medicine and reconstructive surgery	Int Urogynecol J (2007) 18:1347-1350
Sung VW, et al	Graft use in transvaginal pelvic organ prolapse repair	Obstet & Gynecol 2008; 112(5):1131-1142
Sung VW, Schleinitz MD, et al	Comparison of retropubic vs transobturator approach to midurethral slings: a systematic review and meta-analysis	The American Journal of Obstetrics & Gynecology, 197:3-11, 01-Jul-07
Svabik K, Martan A, et al	Ultrasound appearances after mesh implantation--evidence of mesh contraction or folding?	Int Urogynecol J (2011) 22:529-533
Svenningsen, Rune	Long-term follow-up of the retropubic tension-free vaginal tape procedure	Int Urogynecol J (2013) 24:1271-1278 DOI 10.1007/s00192-013-2058-2
Sweat SD, et al	Polypropylene mesh tape for stress urinary incontinence: complications of urethral erosion and outlet obstruction	J Urology 2002; 168:144-146
Sweat, S., et al	Polypropylene Mesh Tape for Stress Urinary Incontinence: Complication of Urethral Erosion and Outlet Obstruction	The Journal of Urology, Vol. 168, 144-146, (July 2002)
Szarnicki RJ	Polypropylene Suture Fracture	Ann Thorac Surg 1985 April; 39(4):400
Tahseen S, et al	Effect of transobturator tape on overactive bladder symptoms and urge urinary incontinence in women with mixed urinary incontinence	Obstet Gynecol 2009; 113:617-23
Tamai A, et al	TVT and TOT: a comparison between these two techniques based on our clinical experience	Urologia 2008 October-December; 75(4): 232-236
Tamussino K, Hanzal E, et al	Transobturator tapes for stress urinary incontinence: Results of the Austrian registry	Am J Obstet Gynecol 2007; 197:634e1-634e5
Tamussino K, Tammaa A, et al	TVT vs. TVT-O for primary stress incontinence: a randomized clinical trial	Int Urogynecol J (2008) 19 (Suppl 1):S1-S166
Tamussino KF, et al	Tension-Free Vaginal Tape Operation: Results of the Austrian Registry	Obstet Gynecol 2001;98:732-6
Tarcan T, et al	Safety and Efficacy of retropubic or transobturator midurethral slings in a randomized cohort of Turkish women	Urol Int Published online Aug 20, 2014
Taub, D., et al	Complications Following Surgical Intervention for Stress Urinary Incontinence: A National Perspective	Neurourology and Urodynamics 24:659-605 (2005)
Téllez Martínez-Fornés M, Fernánde	A three year follow-up of a prospective open randomized trial to compare tension-free vaginal tape with Burch colposuspension for treatment of female stress urinary incontinence	Actas Urologicas Españolas 2009 Nov;[Deleted Object](10):1088-96

## LITERATURE

Author	Description	Journal Citation
Teo R, Moran P, Mayne C, and Tince	Randomized Trial of Tension-free Vaginal Tape and Tension-free Vaginal Tape-Obturator for Urodynamic Stress Incontinence in Women.	Journal of Urology ,185: 1350-5 ,22-Feb-11
The American College of Obstetricia	Committee Opinion No. 513: Vaginal Placement of Synthetic Mesh for Pelvic Organ Prolapse	Obstetrics & Gynecology,118:1459-64,01-Dec-11
The American College of Obstetricia	"Grants, Sponsorships, and Other Support - 2010"	The American Congress of Obstetricians and Gynecologists website,01-Aug-12
The American College of Obstetricia	"Grants, Sponsorships, and Other Support - 2009 "	The American Congress of Obstetricians and Gynecologists website,01-Jan-09
The American College of Obstetricia	"Grants, Sponsorships, and Other Support - 2011"	The American Congress of Obstetricians and Gynecologists website,01-Mar-13
The American College of Obstetricia	"Grants, Sponsorships, and Other Support - 2012"	The American Congress of Obstetricians and Gynecologists website,01-Mar-13
The British Association of Urologic	Synthetic Vaginal Tapes for Stress Incontinence Procedure-Specific Information for Patients	
Thompson, M et al	In vivo polypropylene mesh degradation is hardly a myth	Int Urogynecol J 2016 Dec 29
Tijdkink MM, Vierhout ME, et al	Surgical management of mesh-related complications after prior pelvic floor reconstructive surgery with mesh	Int Urogynecol J (2011) 22:1395-1404
Tincello D, Kenyon S, et al	Colposuspension or TVT with anterior repair for urinary incontinence and prolapse: results of and lessons from a pilot randomised patient-preference study (CARPET 1)	BJOG 2009; 116:1809-1814
Tincello DG, Botha T, et al	The TVT Worldwide Observational Registry for Long-Term Data: Safety and Efficacy of Suburethral Sling Insertion Approaches for Stress Urinary Incontinence in Women	Journal of Urology,186: 2310-5,01-Dec-11
Tipton, JS	Obturator neuropathy	Curr Rev Musculoskelet Med. 2008 Dec;1(3-4):234-7
Tirlapur SA, Vlismas A, et al	Nerve stimulation for chronic pelvic pain and bladder pain syndrome: a systematic review	Acta Obstetricia et Gynecologica Scandinavica,,24-May-13
Tommaselli GA, D'Afiero A, et al	Efficacy of a modified technique for TVT-O positioning: a twelve-month, randomized, single-blind, multicenter, non-inferiority study.	Eur J Obstet Gynecol Reprod Biol. (2013) 167: 225-229
Tommaselli GA, D'Afiero A, et al	Effect of Modified Surgical Technique for the Positioning of TVT-O on Post-Operative Pain	Int Urogynecol J (2011) 22 (Suppl 1) S110
Tommaselli GA, D'Afiero A, et al	ICS Abs 791 Single incision tension-free vaginal tape (TVT-Secur®) in the treatment of female stress urinary incontinence.	International Continence Society Mtg 2010

## LITERATURE

Author	Description	Journal Citation
Tommaselli GA, D'Afiero A, et al	Tension-free vaginal tape-O and -Secur for the treatment of stress urinary incontinence: a thirty-six-month follow-up single-blind, double-arm, randomized study.	J Minim Invasive Gynecol (2013) 20, 198-204
Tommaselli GA, Di Carlo C, et al	Efficacy and Safety of TVT-Secur in the Treatment of Female Stress Urinary Incontinence: 1-year follow-up	The International Urogynecology Journal,21:1211-7,26-May-10
Tommaselli GA, et al	Comparison of TVT-O and TVT-Abbrevio for the surgical management of female stress urinary incontinence: a 12-months preliminary study	Int J Gyencol Obstet (2012) 119: Supp 3: S504
Tommaselli GA, et al	Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis	Int Urogynecol J 2015;26:1253-1268
Tommaselli GA, Formisano C, Di Car	Effects of a modified technique for TVT-O positioning on postoperative pain: single-blind randomized study.	Int Urogynecol J. (2012) 23:1293-9.
Touboul, C.	Perneal approach to vascular anatomy during transobturator cystocele repair	BJOG 2009; 116:708-712
Trabucco A, et al	A novel composite sling for the treatment of stress urinary incontinence: first clinical experience	J Pelvic Medicine & Surg 2004; 10(2):63-70
Trabucco AF, et al	Nowa beznapiciowa tasma T- sling w leczeniu wysitkowego nietrzymania moczu	Foreign Journal
Trindade MCD, et al	Proinflammatory mediator release in response to particle challenge: Studies using the bone harvest chamber	Biomed Mater Res Appl Biomater 1999; 48:434-439
Trivedi, et al	Understanding Female Urinary Incontinence and Master Management	S. Narayan & Sons 2014
Tseng LH, Wang AC, Lin YH, et al	Randomized comparison of the suprapubic arc sling procedure vs tension-free vaginal taping for stress incontinent women	The International Urogynecology Journal,16:230-5,27-Oct-04
Tunn, R.	Sonomorphological Evaluation of Polypropylene Mesh Implants After Vaginal Mesh Repair in Women With Cystocele or Rectocele	Ultrasound Obstetrics Cynecol 2007; 29:449-452
Turon TJ, et al	Effect of stabilizer and pigment on photo-degradation depth profiles in polypropylene	Polym Degrad Stab 2001; 74:559-568
Turut P, Florin P, et al	Les Complications Dues Au Prolene	Bull.Soc.Opht.France 1981: 8-9
Twiss C and Raz S.	Complications of synthetic mid-urethral slings	laborie.com,,01-Mar-08
Tyan Y, et al	Assessment and characterization of degradation effect for the varied degrees of ultra violet radiation onto the collagen-bonded polypropylene non-woven fabric surfaces	Biomater 2002; 23:65-76
Tzartzeva K, et al	In-depth nano-investigation of vaginal mesh and tape fiber explants in women	IUGA 2014 Abstract 366
Tzartzeva K, Lingam D, et al	In-Depth Nano-Investigation of Vaginal Mesh and Tape Fiber Explants in Women	Study: UT SW Med Center, UT Dallas

## LITERATURE

Author	Description	Journal Citation
UCLA	Clinical Updates - Surgical mesh for pelvic organ prolapse repair the subject of FDA warning	UCLA Clinical Updates webpage 9/19/2012
Ulmsten U, et al	A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence	Int Urogynecol J (1998) 9:2010-213
Ulmsten U, Henriksson L, et al	An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence	The International Urogynecology Journal, 7:81-6, 01-Jan-96
Ulmsten U.	An Introduction to Tension-Free Vaginal Tape (TVT) - A New Surgical Procedure for Treatment of Female Urinary Incontinence	Int Urogynecol J (2001)(Suppl 2):S3-S4
Ulmsten U., et al	Reprint: A Multicenter Study of Tension-Free Vaginal Tape (TVT) for Surgical Treatment of Stress Urinary Incontinence	Int Urogynecol J (1998) 9:210-213 Eth.Mesh.00145084-00145088
Ulmsten, et al	A three-year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence	Br J Obstet Gynaecol (1999) 106: 345-350
Unger, CA, et al	Outcomes following treatment for pelvic floor mesh complications	Int Urogynecol J (2014) 25:745-749
Usher FC, et al	Poly Monofilament. A new, biologically inert suture for closing contaminated wounds	JAMA 1962; 179(10) :780-782
Ustün Y, Engin-Ustün Y, et al	Tension-free vaginal tape compared with laparoscopic Burch urethropexy	J Am Assoc Gynecol Laparosc. 2003 Aug; 10(3):386-9
Valentim-lourenco A, et al	"TORP- comparing the efficacy, execution and early complications of TVT and TVT-0"	International Urogynecology Journal
Valpas A, Kivelä A, et al	Tension-free vaginal tape and laparoscopic mesh colposuspension for stress urinary incontinence	Obstetrics & Gynecology, 2004 July; 104(1):42-49
van der Walt S., et al	The dorsal nerve of the clitoris in relation to urinary incontinence sling procedures	Int Urogynecol J 2017; 28: 119
Van Winkle W Jr, et al	Effect of suture materials on healing skin wounds	Surg Gynecol Obstet 1975; 140(1):7-12
Vassallo, BJ., et al	Management of Iatrogenic Vaginal Constriction	Obstet Gynecol. 2003 Sept; 102(3): 512-20
Velemir L, Amblard J, Jet al	Urethral erosion after suburethral synthetic slings: risk factors, diagnosis, and functional outcome after surgical management	Int Urogynecol J (2008) 19: 999-1006
Versi E	"Gold standard" is an appropriate term	BMJ 1992; 305:187
Vervest HAM, Bisseling TM, et al	"The prevalence of voiding difficulty after TVT, its impact on quality of life, and related risk factors."	Int Urogynecol J 2007; 18:173-182
Viereck, Volker ; Rautenberg, et al	Midurethral Sling Incision: Indications and Outcomes	Int Urogynecol J (2013) 24:645-653
Voeller, GR	New Developments in Hernia Repair	Surg Technol XI: 111-116
Vollebregt, A., et al	Bacterial Colonisation of Collagen-Coated Polypropylene Vaginal Mesh: Are Additional Intraoperative Serility Procedures Useful?	Int Urogynecol J Pelvic Floor Dysfunct. 2009 Nov; 20(11):1345-51

## LITERATURE

Author	Description	Journal Citation
Von Theobald P, Zimmerman CW, et al	New Techniques in Genital Prolapse Surgery	2011 XII, 310 p, Hardcover ISBN: 978-1-84885-135-4
Wadie BS, Edwan A, and Nabeeh AM.	Autologous fascial sling vs polypropylene tape at short-term followup: a prospective randomized study	J Urology, 2005 Sept; 174:990-993
Wadie BS, Mansour A, et al	Minimum 2-year follow-up of mid-urethral slings, effect on quality of life, incontinence impact and sexual function	Int Urogynecol J (2010) 21:1485-1490
Wai CY.	Surgical treatment for stress and urge urinary incontinence.	Obstet Gynecol Clin N Amer 2009;36:509-519
Wai, C.Y.	Patient Satisfaction After Midurethral Sling Surgery for Stress Urinary Incontinence.	Obstet Gynecol (2013) 121:1009-1016
Walsh CA.	TVT-Secur mini-sling for stress urinary incontinence: a review of outcomes at 12 months.	BJU International,108:652-7,14-Jul-11
Walter JE.	SOGC Technical Update No. 254: Transvaginal Mesh Procedures for Pelvic Organ Prolapse. Society of Obstetricians and Gynaecologists of Canada	Journal of Obstetrics and Gynaecology Canada,[Deleted Object]:168-74 ,01-Feb-11
Walters, MD	Percutaneous Suburethral Slings: State of the Art	Presented at the conference of the American Urogynecologic Society, Chicago, 29 pages (Oct. 2001 )
Waltregny D,	New Surgical Technique for Treatment of Stress Urinary Incontinence TVT-Abbrevio: From Development to Clinical Experience	Surg Technol Int (2012) 22:149-157
Waltregny D, de Leval J.	The TVT-obturator surgical procedure for the treatment of female stress urinary incontinence: a clinical update.	Int Urogynecol J (2009) 20:337-348
Waltregny D, Gaspar Y, et al	TVT-O for the treatment of female stress urinary incontinence: Results of a prospective study after a 3-year minimum follow-up	European Urology,53:401-10,21-Aug-07
Waltregny D, Reul O, et al	Inside out transobturator vaginal tape for the treatment of female stress urinary incontinence: interim results of a prospective study after a 1-year minimum followup.	J Urol. 2006 Jun;175(6):2191-5.
Waltregny D, Thomas A, et al	Three year results of a prospective randomized trial comparing the original inside-out transobturator (TVT-O™) Procedure with a modified version of using a shortened tape and reduced dissection for the treatment of female stress urinary incontinence	ICU Abstract 254
Waltregny D, Thomas A, et al	Three year results of a prospective randomized trial comparing the original inside-out transobturator (TVT-O™) procedure with a modified version using a shortened tape and reduced dissection for the treatment of female SUI	Poster #254

## LITERATURE

Author	Description	Journal Citation
Waltregny TA, DeLeval J	One year results of a prospective randomized trial comparing the original inside-out transobturator (TVT-O™) procedure and a modified version using a shortened tape and reduced dissection for the treatment of female stress urinary incontinence [abstract]	Int Urogynecol J (2010) 21 (Suppl 1) S219-S221 IUGA, Abst 153
Wang AC and Chen MC.	Comparison of tension-free vaginal taping versus modified Burch colposuspension on urethral obstruction: a randomized controlled trial	Neurourology and Urodynamics 22:185-190 (2003)
Wang AC, Lee L, Lin C, et al	A histologic and immunohistochemical analysis of defective vaginal healing after continence taping procedures: A prospective case-controlled pilot study	American Journal of Obstetrics and Gynecology (2004) 191, 1868-74
Wang D, et al	Initial experience with acellular human dermal allograft (Repliform) pubovaginal sling for stress urinary incontinence	J Pelvic Med Surg 2004; 10: 23-26
Wang F, Song Y and Huang H.	Prospective randomized trial of TVT and TOT as primary treatment for female stress urinary incontinence with or without pelvic organ prolapse in Southeast China	Arch Gynecol Obstet. 2010 Feb; 281(2) 279-86
Wang W, Zhu L and Lang J.	Transobturator tape procedure versus tension-free vaginal tape for treatment of stress urinary incontinence	International Journal of Gynecology & Obstetrics 104 (2009) 113-116
Wang YJ, Li FP, Wang Q, et al	Comparison of three mid-urethral tension-free tapes (TVT, TVT-O, and TVT-Secur) in the treatment of female stress urinary incontinence: 1-year follow-up.	Int Urogynecol J. 2011 Nov;22(11):1369-74. doi: 10.1007/s00192-011-1445-9. Epub 2011 May 13
Wang, AC	A microbiological and immunohistochemical analysis of periurethral and vaginal tissue in women with de novo urge symptoms after mid-urethral sling procedures-a prospective case-controlled study.	Int Urogynecol J (2008) 19:1145-1150
Ward K, et al	Minimally invasive synthetic suburethral slings: emerging complications	The Obstetrician & Gynaecologist 2005;7:223-232
Ward KL and Hilton P et al	Prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence2	BMJ,325:1-7,13-Jul-02
Ward KL and Hilton P et al	A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: Two-year follow-up	The American Journal of Obstetrics & Gynecology,190:324-31,01-Feb-04
Ward KL and Hilton P.	Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up	BJOG 2008;115:226-233

## LITERATURE

Author	Description	Journal Citation
Weber AM, et al	The standardization of terminology for researchers in female pelvic floor disorders	Int Urogynecol J (2001) 12: 178-186
Wei JT, et al	A Midurethral Sling to Reduce Incontinence after Vaginal Prolapse Repair	N Engl J Med. 2012 June 21; 366(25): 2358-2367.
Wei JT, et al	A Midurethral Sling to Reduce Incontinence after Vaginal Prolapse Repair	N Engl J Med. 2012 June 21; 366(25): 2358-2367. doi:10.1056/NEJMoa1111967.
Welk B, et al	Removal or revision of vaginal mesh used for the treatment of stress urinary incontinence	JAMA Surg. doi:10.1001/jamasurg.2015.2590 Published online September 9, 2015.
Westermann L, Brown A, et al	Delayed Presentation of an Enterocutaneous Fistula After Tension-Free Vaginal Tape Sling	Female Pelvic Reconstr Surg 2011; 17: 258-259
White , R.A., Hirose, F.M., et al.	(1981). Histopathologic observations after short-term implantation of two porous elastomers in dogs.	Biomaterials, 2:171-176.
White RA, et al	Histopathologic observations after short-term implantation of two porous elastomers in dogs	Biomater 1981; 2:171-176
White WM, et al	Robatic sacral colpopexy	Chapter 5; P. Dasgupta et al. (eds.), New Technologies in Urology, 37 DOI: 10.1007/978-1-84882-178-1_5, © Springer-Verlag London Limited 2010
Whiteside JL and Walters MD.	Anatomy of the obturator region: relations to a trans-obturator sling	The International Urogynecology Journal,15:223-6,24-Feb-04
Wijffels SAM, et al	Transurethral mesh resection after urethral erosion of tension-free vaginal tape: report of three cases and review of literature	Int Urogynecol J (2009) 20:261-263
Willard, FH, et al	The Neuroanatomy of Female Pelvic Pain	Pain in Women: A Clinical Guide, Chapter 2
Willert HG, et al	Osteolysis in Alloarthroplasty of the hip. The role of ultra-high molecular weight polyethylene wear particles	Clin Orthop Relat Res 1990; 258:95-107
Williams	Mechanisms of biodegradation of implantable polymers	Clin Mater 1992;10:9-12
Williams D.	Review Biodegradation of surgical polymers	Journal of Materials Science. 1982; 17:1233-1246
Williams DF	Biodegradation of surgical polymers	J Mater Sci 1982; 17:1233-1246
Williams DF, et al	Biodeterioration/Biodegradation of Polymeric medical devices in situ	Inter Biodeterior Biodegradation 1994; 34(2): 95-130

## LITERATURE

Author	Description	Journal Citation
Williams, DF, et al	The biodegradation of surgical polymers	Polyurethanes in Biomedical Engineering edited by H. Planck, et al, Elsevier Science Publishers B.V., Amsterdam, 1984
Wilson, C, et al	Short-term efficacy of transobturator sling in women veterans with a history of sexual trauma	MAAUA 68th Annual Meeting Abstracts (2010)
Withagen MI, Milani AL, et al	Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapsed: a randomized controlled trial.	Obstetrics & Gynecology,117:242-50 ,01-Feb-11
Wolter CE, Starkman JS, et al	Removal of transobturator midurethral sling for refractory thigh pain.	Urology (2008) 72: 461.e1-461.e3
Wood,AJ	Materials characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient	J Mater Sci: Mater Med (2013) 24:1113-1122
Wróbel A, et al	Clinical effectiveness of transobturator midurethral sling (T-sling) with additional 2-point tape fixation performed on an outpatient and inpatient basis	Fineköl Pol 2014;85(11):833-837
Wu JM, Kawasaki A, et al	"Predicting the number of women who will undergo incontinence and prolapse surgery, 2010 to 2050. "	The American Journal of Obstetrics & Gynecology,205:230.e1-5 ,02-Apr-11
Wyczolkowski, M., et al	Reoperation After Complicated Tension-Free Vaginal Tape Procedures	The Journal of Urology, Vol 166, 1004-1005 (Sept 2001)
Yahi YH, et al	Electronic Microscopy Study of Alterations of Meshes Explanted for Complications in SUI or POP Surgery	Int Urogynecol J 2007; 18(Suppl 1): S6
Yakimets I, et al	Effect of photo-oxidation cracks on behaviour of thick polypropylene samples	Polym Degrad Stab 2004; 86:59-67
Yang C, et al	Presentation Number: Oral Poster 18 Anchor extraction forces for single-incision slings: strength comparison in a rabbit model	Female Pelvic Med & Reconstr Surg (2011) 17(5)2:S92
Yang CH, Chan PH, Lai SK, et al	A retrospective study comparing tension-free vaginal tape and transobturator suburethral tape for surgical treatment of female stress urinary incontinence --- a preliminary report.	J Chin Med Assoc. 2007 Dec;70(12):541-4. doi: 10.1016/S1726-4901(08)70057-1.
Yang CQ, et al	Photo and thermal-oxidation of the nonwoven polypropylene fabric studies by FT-IR photoacoustic spectroscopy	J Appl Polym Sci 1994; 51:389-397
Zahn C et al	Anatomic comparison of two transobturator tape procedures.	Obstet Gynecol 2007;109:701-6.
Zhang Y, Jiang M, Tong XW, et al	The comparison of an inexpensive-modified transobturator vaginal tape versus TVT-O procedure for the surgical treatment of female stress urinary incontinence.	Taiwan J Obstet Gynecol. 2011 Sep;50(3):318-21. doi: 10.1016/j.tjog.2011.01.033

## LITERATURE

Author	Description	Journal Citation
Zhong C, Yuan C, Guang-hui D, et al	Comparison of three kinds of midurethral slings for surgical treatment of female stress urinary incontinence.	Urologia 2010;77(1):37-42
Zhu L, Lang J, Hai N, and Wong F.	Comparing vaginal tape and transobturator tape for the treatment of mild and moderate stress incontinence	International Journal of Gynecology & Obstetrics (2007) 99, 14-17
Zolotarevova E, et al	Distribution of polyethylene wear particles and bone fragments in periprosthetic tissue around total hip joint replacements	Acta Biomaterialia 2010; 6(9): 3595-3600
Zoorob, D. and M. Karram	Management of mesh complications and vaginal constriction: a urogynecology perspective	Urol Clin North Am, 2012. 39(3): p.413-8
Zuckerman DM., et al	Medical Device Recalls and the FDA Approval Process	Arch Intern Med 2011;17(11): 1006-1011 Published Online February 14, 2011
Zugor V, Labanaris AP, et al	"TVT vs. TOT: a comparison in terms of continence results, complications and quality of life after a median follow-up of 48 months. "	Int Urol Nephrol 42, 915-20 (2010)
Zullo MA, Plotti F, et al	One-year follow-up of tension-free vaginal tape (TVT) and trans-obturator suburethral tape from inside to outside (TVT-O) for surgical treatment of female stress urinary incontinence: a prospective randomised trial.	European Urology,51:1376-82,07-Nov-06
Zumbe J., Porres D., Degiorgis PL.	Obturator and thigh abscess after transobturator tape implantation for stress urinary incontinence.	Urol Int. (2008); 81:483-485
Zwarenstein M, et al	Improving the reporting of pragmatic trials: an extension of the CONSORT statement	BMJ 2008; 337:12390
Zycynski HM, Carey MP, et al	One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device	Am J Obstet Gynecol 2010; 203:587.e1-8

<b>DEPONENT</b>	<b>DATE</b>
Angelini, Laura, Transcripts and Exhibits	All dates
Arnaud, Axel, MD Transcripts and Exhibits	All dates
Barbolt, Thomas A., Ph.D Transcripts and Exhibits	10/10/2012; 08/04/2013; 08/15/2013; 01/07/2014; 01/08/2014
Batke, Boris Transcripts and Exhibits	8/1-2/2013
Beath, Catherine Transcripts and Exhibits	07/11-12/2013
Burkley, Dan Transcripts and Exhibits	5/22/2013; 5/23/2013
Chen, Meng, MD Transcripts and Exhibits	10/29-30/2013
London-Brown, Allison Transcripts and Exhibits	All dates
Hart, James D., MD Transcripts and Exhibits	09/17/2013; 12/20/2013
Hellhammer, Brigitte, MD Transcripts and Exhibits	09/11-12/2013
Hinoul, Piet Transcripts and Exhibits	All dates
Holste, Joerg Transcripts and Exhibits	07/29-30-2013
Horton, Ron Transcripts and Exhibits	7/1/2015
Isenberg, Richard, MD Transcripts and Exhibits	11/5/13 and 11/6/13
Divilio, Thomas Transcripts and Exhibits	All dates
Elbert, Katrin, PhD Transcripts and Exhibits	12/23/2014
Kirkemo, Aaron, Transcripts and Exhibits	All dates
Kammerer, Gene, Transcript and Exhibits	All dates
Lin, Susan, Transcripts and Exhibits	3/12-13/2013; 05/3,6/2013; 08/01/2013
Lamont, Daniel J. Transcript	4/3-4/2013; 9/11/2013
O'Grady Terence J.	8/25/2016
Owens, Charlotte Transcript and Exhibits	9/12/2012; 6/20/2013
Rink, Ronald L.	7/12/2016; 08/29/2016
Robinson, David Transcripts and Exhibits	07/24-25/2013; 09/11/2013
Selman, Renee Transcript and Exhibits	6/21/2013
Smith, Dan, Transcripts and Exhibits	05/15-16/2013; 06/04- 05/2013; 08/20-21/2013
Vailhe, Christophe, Ph.D., Transcripts and Exhibits	06/20-21/2013
Wilson, Anne, MBA	9/17/2015
Woods, Michael P., MD., Transcript and Exhibits	10/5/2015
Weisberg, Martin, MD Transcripts and Exhibits	All dates
McCoy, Sheri Transcripts and Exhibits	All dates
Yale, Mark, Transcript and Exhibits	8/7/2013
Scheich, Martina Transcript and Exhibits	All dates
Trial Testimony of Piet Hinoul - Batiste v. Ethicon	3/26/14; 3/27/14; 3/28/14
Jones, Scott Transcript and Exhibits	6/9/2014
Rovner, Eric Transcript and Exhibits	All dates
Elbert, Katrina Transcript and Exhibits	12/23/2014
Elbert, Katrina Trial Transcript and Exhibits From Perry v. Ethicon	
Testimony and Exhibits from Batiste v. Ethicon Trial	

Plaintiff and Defendant Deposition Designation Cuts	
Klinge de bene esse testimony and exhibits	
<b>Expert Witness Reports</b>	
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